Proficiency Testing in US Clinical Laboratories: Perception, Practices and Potential for Expanded Utility

Request for Approval of New Data Collection
Supporting Statement A

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Contact:
Rex Astles, PhD
Division of Laboratory Science and Standards
Laboratory Science, Policy, and Practice Program Office
Centers for Disease Control and Prevention
1600 Clifton Rd.
MS F-11
Atlanta, Georgia 30333
Phone: 404.498.2296
Fax: 404.498.2219
Email: JAstles@cdc.gov

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Proficiency Testing Perception, Practices and Potential for Expanded Utility:
Survey of a Sample of CLIA Laboratories
Request for Approval of New Data Collection
Part A

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

This is a request for OMB approval of a new data collection, Proficiency Testing Perception, Practices and Potential for Expanded Utility. CDC is requesting an eighteen month approval to collect the data. This data collection falls under the Title 42 Public Health and Welfare Authorization Legislation included as Attachment A.

This project is part of a cooperative agreement between the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL). Based upon prior work conducted under this cooperative agreement, it appears that many laboratories use proficiency testing (PT) results from commercial PT programs not only to meet Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements, but also as an internal mechanism for quality improvement. The primary focus of this data collection is to conduct a systematic analysis to understand which types of laboratories follow PT good laboratory practices (GLPs) and to identify which kinds of laboratories could be targeted to promote PT GLPs, for example based upon include laboratory testing volume and other characteristics of the laboratory including its size in terms of annual test volume or type (for example, physician office laboratory). Since laboratories already pay for PT materials, the use of PT for quality improvement purposes has the potential to further improve laboratory quality at no additional cost to US clinical laboratories. For the laboratories that perform microbiology testing, the survey will ask a series of questions on the use of PT in microbiology and ways that it may be improved.

In addition, by conducting this analysis APHL and CDC hope to learn more about the types of laboratories that do not comply with the CLIA PT requirements and correlations with noncompliance, for example whether certain laboratory types, size, or locations are more at risk for non-compliance. The survey population frame is 20,500 Certificate of Compliance laboratories and 16,800 Certificate of Accreditation laboratories. All of these laboratories are required to perform PT in accordance with CLIA.

Further, the Centers for Medicare & Medicaid Services (CMS) and CDC are currently collaborating to revise the CLIA regulations to update the list of non-microbiological tests (analytes) for which PT is required, and to update the requirements for microbiology PT. Both of these changes are expected to have some impact on clinical and public health laboratories, but CDC has very little data to estimate the impact. Information to be collected concerning the

perceived benefits and burden of performing PT will be needed to complete the regulatory impact analysis. The Department of Health and Human Services knows very little about the perceived costs and benefits of PT and this survey will provide an opportunity to learn about the perceived value versus costs of performing PT.

The first phase of this project was conducted by APHL through focus group research in 2011. The focus groups explored how clinical and public health laboratories perceived commercial PT programs and explored the ways in which the laboratories used PT GLPs to assure and improve the quality of their testing. This second phase of the research study will include administering a survey to build on the preliminary findings from the focus group research and help identify the types of laboratories that would benefit from learning about additional uses for PT, and providing information about PT GLP's to these laboratories in a strategic and targeted way. The 60-Day Federal Register Notice for this work was published on August 7, 2012 and is included as Attachment B. No comments were received.

Privacy Impact Assessment

Overview of the Data Collection System

The survey questionnaire will be programmed through Survey Monkey. This is a commercial software system which supports compliance with Section 508 of the American Rehabilitation Act. Survey Monkey has been used successfully on many public health projects to collect survey data. Extensive internal testing of the survey questionnaire and associated field protocols will be performed prior to the actual launch of the survey. The web-based survey will be administered and maintained by a contractor to APHL. The screen shots for the Survey Monkey survey are included as Attachment C.

Survey respondents will use one of two identifiers to access and take the survey. The survey invitation and follow-up postcard will include a unique 8-digit identifier which will correspond to their laboratory and enable the respondent to log in to the survey. Alternatively respondents can log in to the survey using their laboratory's CLIA number which is the number assigned to every CLIA certified laboratory. Regardless of whether the 8-digit unique identifier on the postal letter and postcard or the CLIA number is used, there will be a lock-out feature ensuring only one response per laboratory. This will also enable APHL to track the number of responses.

Both the 8-digit unique identifier on the mailings and the CLIA number will link the responses to the CMS Online Survey Certification and Reporting (OSCAR) database. The OSCAR database contains demographic information on each laboratory as mentioned in the 30-day Federal Register Notice included as Attachment D, and will enable the APHL contractor to analyze the data by demographic criteria including: rural/urban setting, size and type of laboratory, and laboratory testing specialty.

The APHL contractor will retain demographic characteristics matched from the OSCAR database for the sample record. However, all identifying information including the CLIA number and alternative identification number will be removed before an analysis dataset is released to APHL and reported for both internal and external purposes. All data will be reported

in the aggregate. All raw data files minus the CLIA numbers and alternate identifications will be provided to APHL and CDC for further analysis, if necessary.

Items of Information to be Collected
The survey questions will include multiple choice, Likert scale questions and an open-ended question relating to laboratorians' perceptions and practices concerning PT. The survey will also include questions on the laboratory use of GLPs for PT. The results will be used to guide the development of educational materials and to identify target populations to provide information on PT GLPs. No sensitive information is requested at any point in the survey.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age
The information collection will not involve a website with content directed at children less than 13 years of age.

During the data collection process, respondent information will be kept secure. No Personally Identifiable Information (PII)/ IIF is being collected from respondents. The survey does not ask for any information related to individuals. The survey asks for information regarding laboratory work and processes. Survey responses will be submitted electronically, and neither the survey operations staff nor subsequent data analysts will have access to the identities of the respondents. No laboratory identifiers will be retained in the final survey data set.

See Information Collection Request Worksheet Part 1 as Attachment E or Information Collection Details Worksheet Part 2 as Attachment F for additional information.

2. Purpose and Use of Information Collection

Privacy Impact Assessment

During the data collection process, respondent information will be kept in a secure, password-protected database. The survey primarily asks for information regarding laboratorians' use of and opinions on PT. The survey will be completed through a web-based survey system: Survey Monkey. Neither the survey operations staff nor subsequent data analysts will have access to the identities of the respondents or the laboratories completing the survey. The unique 8-digit identifier and/or CLIA number assigned to each laboratory will be used only initially to establish a link to demographic information for the laboratory. The data will be presented with findings in the aggregate. No personal or laboratory identifiers will be retained in the final survey dataset. The Privacy Act Checklist has also been included as Attachment G.

3. Use of Improved Information Technology and Burden Reduction

The survey will use the Internet for web-based data collection as most laboratorians have access to a computer either at work or at home. The laboratories will receive a survey notification and invitation letter via postal mail with instructions on how to complete the web-based survey. See Attachment H for survey invitation letter. The survey invitation is being sent by postal mail since no repository exists for laboratory email addresses. In addition the follow-up postcard will also

include instructions on how to complete the web-based survey. See Attachment I for follow-up postcard language. All data from the survey will be stored in and accessed from an electronic data management system. No paper forms will be submitted to CDC.

4. Efforts to Identify Duplication and Use of Similar Information

APHL and CDC are confident that this work is sufficiently unique as to not duplicate other efforts.

Our review of the literature for previous surveys concerning how clinical laboratories use and perceive PT revealed nothing that was remotely similar to the survey questions we propose. Because CDC Division of Laboratory Science and Standards is aware of efforts by CMS and other parties that have an interest in this field, we are certain that no similar surveys have occurred since CLIA was implemented and no duplicative surveys are being planned by others. Interest has been demonstrated in the anticipated results from this survey. Specifically, the editor of Medical Laboratory Observer, a peer-reviewed journal, is eager to publish results for its readers, who include laboratory professionals who may benefit from learning about PT GLPs.

5. Impact on Small Businesses or Other Small Entities

While some survey respondents may be employed in small laboratories or in small physician office laboratories, it is not possible to estimate exactly how many responding laboratories would be considered small businesses because this information is not provided in the OSCAR database. We would likely estimate that nearly all Certificate of Accreditation laboratories do not qualify as small businesses because they tend to be high-volume settings, and typically include hospital and reference laboratories. On the other hand, the Certificate of Compliance laboratories do tend to be smaller facilities. If the response rate from these laboratories is approximately 80% as hoped, then there would be approximately 16,400 small businesses impacted, at maximum.

In order to reduce respondent burden for all respondents, a simple and accessible survey format will be used. The survey will be accessible via the Internet using conventional software and will be available for respondents to take at their convenience either at home or in the office. The survey will continue to be advertised in trade journals to ensure the maximum response rate. See Attachment J for language to be used in trade journals to advertise the survey. The web-based survey site will be available for one month and will be accessible 24 hours per day. The survey includes 26 questions, and respondents are not asked to provide any extraneous information other than the core survey questions related to laboratory PT practices.

6. Consequences of Collecting the Information Less Frequently

This survey will be fielded only once under the research plan.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances that require the information to be collected in any of the formats identified, and the request fully complies with regulations.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. As required by 5 CFR 1320.8 (d), a notice of this proposed data collection appeared in the Federal Register /Vol. 77, No. 152 /Tuesday, August 7, 2012. No comments were received from the public.

B. The following individuals were consulted during the development of the study methods and data collection instruments.

John S. Hancock
Statistical Consultant
1445 Monroe Dr. NE Unit 27c
Atlanta Ga. 30324
Phone 404-713-4119
Email: jhancock1944@yahoo.com

9. Explanation of Any Payment or Gift to Respondents

As a token of appreciation for completing the survey, the respondents will have the chance to enter a raffle to win one of 50 APHL teleconferences. The one-hour teleconference will be offered as either a live or recorded teleconference. The teleconferences will address relevant, contemporary issues in laboratory testing, and laboratories will have the opportunity to choose one that best meets their needs. All staff at the winning laboratory will be eligible to participate in the teleconference and to earn continuing education credits from doing so. The teleconference is valued at $105 though CDC will only pay $85 per teleconference to cover APHL's costs. A list of current APHL teleconference options is available at this website: http://www.aphl.org/training/teleconf/pages/default.aspx

In order to enter the random raffle drawing for a chance to win one of the APHL teleconferences, participants will be asked to enter their email address on a new screen after the survey closes. This will be done to ensure that no identifying information including the respondent's email address will be connected to the survey. All 50 teleconferences will be awarded and must be used by September 30, 2013. A list of the winners for the teleconferences will be made available through APHL. The teleconference was selected as a sufficiently small incentive so as to not represent an undue compensation or possibly have a coercive influence on respondents. In

addition, if won, the incentive would benefit the entire laboratory rather than only the individual completing the survey.

10. Assurance of Confidentiality Provided to Respondents

Privacy Impact Assessment

This submission has been reviewed by CIO who determined that the Privacy Act does not apply. During the data collection process, respondent information will be kept secure. No IIF is being collected from respondents. The survey does not ask for any information related to individuals. The survey primarily asks for information regarding laboratorians' work and processes. Survey responses will be submitted electronically, and neither the survey operations staff nor subsequent data analysts will have access to the identities of the respondents. No identifiers will be retained in the final survey dataset. This study is not considered human subjects research. See Attachment K.

A) Respondents to the survey will be assigned unique codes for their laboratories (the number on the survey invitation), and these codes will not contain personal identifying information. The codes will be used to analyze the data by categories including: rural/urban setting, size and type of laboratory, and laboratory testing specialty. In the final report all information will be reported in the aggregate without any personal or laboratory identifiers.
B) Survey responses received by the contractor will be stored in a secure, password-protected database.
C) Since no personally identifiable information will be collected or used, consent will not be necessary.
D) The survey will inform participants responses are voluntary and explain that laboratories will remain anonymous.
E) If the data are passed onto CDC or APHL for additional analysis, the survey responses will similarly be stored in a secure, password-protected database at the CDC and APHL facilities.

11. Justification for Sensitive Questions

Information on criminal behavior, sexual behavior and attitudes, alcohol or drug use, religious beliefs, and race and ethnicity will not be collected. Data security will be ensured according to the information provided above in Section 10.

12. Estimates of Annualized Burden Hours and Costs

A. Approximately 37,300 clinical laboratories will be targeted and solicited to take the on-line survey. Each laboratory is permitted to submit only one completed survey. Preliminary pilot testing indicates completion of the on-line survey will take approximately 20 minutes. Assuming an 80% response rate, there would be 29,840 respondents.

There are many different kinds of laboratories that participate in PT and these will all be included in the targeted group. These laboratories differ greatly in their characteristics,

including size, staffing, test menus offered, and so forth. We believed it would be difficult to get a representative sample that would accurately reflect the national composition, so we opted not to sample, but offer the survey to all laboratories that perform PT.

Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (hours)	Total Burden Hours
Laboratorians	Laboratory Practices	29,840	1	20/60	9947
Total					9947

B. The total cost burden for respondents is estimated as follows: with a total burden of 9947 hours, the total cost of the respondents' time to respond to the proposed survey is estimated to be $223,211. The average hourly wage rate for laboratorians was obtained from the Bureau of Labor with their most recent May 2011 data at http://www.bls.gov/oes/current/oes292012.htm (accessed October 30, 2012).

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Laboratorians	9947	$22.44	$223,211
Total			$223,211

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no other annual cost burdens.

14. Annualized Cost to the Government

The total annualized cost to the Government of this survey is comprised of CDC staff support and consultation throughout the design, survey administration, and analysis and reporting. CDC

staff costs are estimated using the estimated hours of time of support and pay rates from the GS pay scale for Atlanta (http://www.opm.gov/oca/11tables/html/atl_h.asp) and assumed a team of six with GSA pay scales of Grade 11 (1 person); Grade 13 (4 people at 10%, 5%, 5% and 5%; and Grade 14 at 15%, for a total of 1,040 hours.

To calculate the amount of CDC staff time and salaries, we assumed that the project lead, Dr. Astles (GS 14 salary) would be in charge interactions with APHL concerning the survey, validation of results, and writing a report for peer-reviewed scientific publication; he will work approximately 6 hours per week on the survey, analysis and publication. A DLSS staff member in the commissioned corps (approximately GS 13) will be in charge of descriptive data analysis, generating tables, graphs, etc. He will work at approximately 4 hours per week, or 10% of an FTE. Three other individuals who are compensated at a GS 13 rate will work 2hours per week, or 5% of an FTE. Another DLSS staff who is paid at GS 11 will work 2 hours per week, or 5% of an FTE.

The cost to the Federal Government is $54,032.

Cost Component	Total Cost
CDC staff salaries and overhead	$54,032
Total	$54,032

15. Explanation for Program Changes or Adjustments

This is new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Publication

The goal is to present the results from this survey at national meetings and to develop a manuscript on the findings for submission to a peer-reviewed scientific journal. Manuscripts will also include a discussion of potential biases and other limitations of the project. Additionally, results may be used for ongoing planning requirements of the CDC Laboratory Science, Policy, and Practice Program Office.

Project time schedule

The following table outlines the series of steps and the timeframe for completing the survey research. Subsequent publication of results in peer-reviewed scientific journals is not included as part of the basic survey operations time schedule.

Project Time Schedule	Date
Finalize web survey programming	1 month after OMB approval
Obtain and construct sample	1 month after OMB approval
Start survey	2 months after OMB approval
Complete data collection	4 months after OMB approval
Initial data analysis results	5 months after OMB approval
Draft survey report	7 months after OMB approval
Finalize survey report	12 months after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The proposed survey instrument will display the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

None