Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB Control Number: 0920-0974)

TITLE OF INFORMATION COLLECTION: Individualized Quality Control Plan Workbook Survey

PURPOSE: In May 2015, the Centers for Disease Control and Prevention (CDC) in collaboration with the Centers for Medicare & Medicaid Services (CMS) released the **"Individualized Quality Control Plan (IQCP): A Step-By-Step Guide",** which is available both in print and electronically (https://wwwn.cdc.gov/clia/Documents/IQCP%20Layout.pdf). This workbook provides a voluntary guide to assist laboratories in developing IQCP, which is an alternate quality control (QC) option under the Clinical Laboratory Improvement Amendments (CLIA) regulations for most nonwaived testing. CDC Division of Laboratory Systems (DLS) intends to assess the utility of this workbook and its components in helping laboratories evaluate the quality of their testing procedures and meet CLIA requirements if they choose to develop an IQCP. Additionally, CDC DLS would like to assess the user satisfaction of the workbook, as well as its scope of awareness and distribution. The evaluation results will assist DLS in evaluating the usefulness of the workbook as well as the marketing and distribution activities for future improvements.

DESCRIPTION OF RESPONDENTS: Personnel working in moderate complexity laboratories and physician office laboratories who attended Centers for Medicare & Medicaid Services sponsored webinar sessions and/or who have contacted CDC directly and requested hard copies of the IQCP workbook. We anticipate that 50% of those solicited will respond. The survey link will remain active for 6 months (180 days). A follow-up email solicitation will be sent (in the same manner as the initial email), every 8 weeks until the end of the 6 month survey period, in order to encourage greater participation.

TYPE OF COLLECTION: (Check one)

[ ] Customer Comment Card/Complaint Form
[ ] Usability Testing (e.g., Website or Software
[ ] Focus Group
[X] Customer Satisfaction Survey
[ ] Small Discussion Group
[X] Other: Online survey

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Sonya T. Strider

To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [ ] Yes [X] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [ ] No

Gifts or Payments: Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [X] No

BURDEN HOURS

Category of Respondent	**No. of Respondents**	**Participation Time**	**Burden**
Individuals and households	0	0	0
Private sector	500	10/60	84
State, local, tribal government	0	0	0
Federal government	0	0	0
Totals	**500**	10/60	**84**

FEDERAL COST: The estimated annual cost to the Federal government is $8,500

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe? [X] Yes
   [] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

Respondents will be identified from laboratory personnel who attended CMS-sponsored IQCP webinars or requested IQCP workbooks, either by mail or by telephone. Email addresses were obtained from webinar participants and those requesting IQCP workbooks by email. An email announcement will be sent directly to those who have requested the IQCP workbooks with a link to the IQCP Workbook Epi Info Survey tool, requesting that they complete the IQCP survey. Additionally, the survey link will be posted on the CDC CLIA website for easy access when obtaining the workbook from the website.

The same email announcement will be sent by the Medical Learning Network to personnel working in moderate complexity laboratories and physicians' office laboratories who participated in the CMS-sponsored webinars, providing the link to the voluntary survey. All

participants will be informed that participation in the survey is completely voluntary. The survey will remain open for participation for six months after the initial release date.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
    [X] Web-based or other forms of Social Media
    [ ] Telephone
    [ ] In-person
    [ ] Mail
    [ ] Other, Explain
2. Will interviewers or facilitators be used? [ ] Yes [X] No

Please make sure that all instruments, instructions, and scripts are submitted with the request.

Instructions for completing Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback"

TITLE OF INFORMATION COLLECTION: Provide the name of the collection that is the subject of the request. (e.g., Comment card for soliciting feedback on xxxx)

PURPOSE: Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Provide a brief description of the targeted group or groups for this collection of information. These groups must have experience with the program.

TYPE OF COLLECTION: Check one box. If you are requesting approval of other instruments under the generic, you must complete a form for each instrument.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions.

Gifts or Payments: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

BURDEN HOURS:
Category of Respondents: Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households;(2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected.
No. of Respondents: Provide an estimate of the Number of respondents.
Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group)
Burden: Provide the Annual burden hours: Multiply the Number of responses and the participation time and divide by 60.

FEDERAL COST: Provide an estimate of the annual cost to the Federal government.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents. Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.
Please make sure that all instruments, instructions, and scripts are submitted with the request.