Request for Approval under the "Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery" (OMB Control Number: 0910-0697)

A. TITLE OF INFORMATION COLLECTION: Accreditation Scheme for Conformity Assessment (ASCA) Accreditation Body Training Feedback

1. PURPOSE:

The purpose of the information collection is to request feedback on FDA service delivery on the quality/utility of a training session for Accreditation Bodies that participate in the ASCA Pilot program.[1] This feedback is specific to the Accreditation Body training session. Information gathered will not be used for the purpose of substantially informing influential policy decisions. It intends to solicit opinions from respondents who have experience with the program or may have experience with the program in the future. We intend to use the feedback to improve our service delivery for future training sessions.

2. DESCRIPTION OF RESPONDENTS:

Participants are technical assessors who work for accreditation bodies. These respondents attended FDA/CDRH's ASCA Accreditation Body training session.

3. 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.)

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

4. CERTIFICATION: Please read the certification carefully. If you incorrectly certify, OMB will return the generic as improperly submitted or it will be disapproved.

I certify the following to be true:

a) The collection is voluntary.
b) The collection is low-burden for respondents and low-cost for the Federal Government.
c) The collection is non-controversial and does not raise issues of concern to other Federal Agencies.
d) The results are not intended to be disseminated to the public.
e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.

[1]The information collections regarding the ASCA Pilot program itself have been approved under OMB Control Number 0910-0889. For additional background on the ASCA Pilot program, please see FDA's Center for Devices and Radiological Health (CDRH), Standards and Conformity Assessment webpage here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.

f) 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.

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

5. PERSONALLY IDENTIFIABLE INFORMATION (PII): Provide answers to the questions. Note: Agencies should only collect PII to the extent necessary, and they should only retain PII for the period of time that is necessary to achieve a specific objective.

a) Is personally identifiable information (PII) collected? [ ] Yes [X] No
b) If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No
c) If Yes, has an up-to-date System of Records Notice (SORN) been published? [ ] Yes [ ] No

6. GIFTS OR PAYMENT: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

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

BURDEN HOURS: 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 per row.
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)

7. BURDEN**:** Provide the Annual burden hours: Multiply the Number of responses and the participation time and divide by 60.

Category of Respondent	**No. of Respondents**	**Participation Time**	**Burden**
Private Sector: Accreditation Body Training Participants	95	10 minutes	16

8. FEDERAL COST: **[**Provide an estimate of the annual cost to the Federal government.]

There is NO estimated annual cost to the Federal government.

B. STATISTICAL METHODS

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.

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?

Accreditation bodies are invited to self-identify for participation all of their technical assessors for participation.

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.

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.

REQUESTED APPROVAL DATE: January, 2021

NAME OF PRA ANALYST:

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