OMB Control No. 0910-0697 Expiration Date: 12/31/2023

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control for this information collection is 0910-0697 and the expiration date is 12/31/2023. The time required to complete this information collection is estimated to average 10 minutes per response, including the time for reviewing instructions and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestion for reducing burden to PRAStaff@fda.hhs.gov.

Accreditation Scheme for Conformity Assessment (ASCA) Accreditation Body Training Feedback

Thank you for your participation in the ASCA Pilot accreditation body training. As this is a new program for the FDA, we ask that you help us improve future training by answering a few questions. Please give thought to what you learned over the course of the sessions and be candid in your assessment and your feedback. Your data will be kept secure to the fullest extent allowed by law.

On a scale of 1 to 5, how useful did you find the training (1 being not helpful at all and 5 being very helpful)?

- 1. Do you feel as though the training has adequately prepared you to conduct testing laboratory assessments for the ASCA Pilot? Yes/No. If you answered 'No' please share why you do not feel prepared.
- 2. For participants in the basic safety and essential performance sessions:

Did the sessions strike an appropriate balance between the basics of basic safety and essential performance standards and their application to conformity assessment? Yes/No. If you answered 'No' please explain how the FDA can better address that balance.

For participants in the biological evaluation of medical devices sessions:

Did the training reflect sufficient detail for the various standards and test methods? Yes/No. If your answered 'No' please share the standards and/or methods that need additional detail.

- 3. What topics or sessions were most helpful?
- 4. What topics or sessions were least helpful?
- 5. What would you like to learn more about?