The FDA Accreditation Scheme for Conformity Assessment Program (ASCA)

PJLA offers third-party accreditation services to Conformity Assessment Bodies (i.e. Testing and/or Calibration Laboratories, Reference Material Producers, Field Sampling and Measurement Organizations and Inspection Bodies). This procedure outlines PJLA's accreditation process and criteria administered to conformity assessments bodies for the **FDA Accreditation Scheme for Conformity Assessment Program (ASCA). This is a Supplemental Procedure to PJLA's Accreditation Procedure (SOP-1). Both procedures shall be followed for the entirety of this accreditation program.**

1.0 SCOPE/PURPOSE

1.1 The FDA Accreditation Scheme for Conformity Assessment Program (ASCA) is a program to protect and promote public health by ensuring medical device testing laboratories are competent to perform tests as outlined in the ASCA Biocompatibility Testing of Medical Devices Guidelines and the Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment criteria documents as well as the ISO/IEC 17025:2017 standard.

1.2 This procedure includes the process for which PJLA carries out its accreditations in accordance with the ASCA program requirements as well as obligations of the CABs participating in the program.

2.0 REFERENCES

2.1 The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

2.2 Biocompatibility Testing of Medical Devices-Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

2.3 Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

3.0 DEFINITIONS

3.1 **Accreditation:** third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

3.2 **Accreditation body:** authoritative body that performs accreditation

3.3 **ASCA-accredited testing laboratory:** testing laboratory that has been granted ASCA Accreditation by FDA.

3.4 **ASCA-recognized accreditation body:** accreditation body that has been granted ASCA Recognition by FDA.

3.5 **ASCA Accreditation:** status granted by FDA to testing laboratories that demonstrate competence in testing via the application process.

3.6 **ASCA Recognition:** status granted by FDA to accreditation bodies that demonstrate competence in accreditation activities via the application process.

3.7 **ASCA summary test report:** documentation that summarizes the testing conducted by an ASCA-accredited testing laboratory within the scope of its ASCA Accreditation

3.8 **ASCA summary test report:** specific to the ASCA Pilot that includes the information recommended in the standards specific ASCA Pilot guidance documents.

3.9 **Assessment:** systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.

3.10 **Conformity assessment:** demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled; note that the subject field of conformity assessment may include testing, inspection, and certification, as well as accreditation of conformity assessment bodies.

3.11 **Conformity assessment body (CAB):** body that performs conformity assessment services

3.12 **Declaration of conformity (DOC):** attestation made by a medical device manufacturer, in accordance with section 514(c)(1)(B) of the FD&C Act, regarding whether a device conforms with an FDA-recognized consensus standard.

3.13 **Determinations by testing laboratories:** test results

3.14 **Extending accreditation:** adding conformity assessment activities to the scope of accreditation

3.15 **Extending ASCA Accreditation:** adding FDA-recognized consensus standards and test methods to a testing laboratory's scope of ASCA Accreditation.

3.16 **Extending ASCA Recognition:** adding FDA-recognized consensus standards and test methods to an accreditation body's scope of ASCA Recognition

3.17 **Scope of accreditation**: specific conformity assessment activities for which accreditation is sought or has been granted

3.18 **Scope of ASCA Accreditation**: list of FDA-recognized consensus standards and test methods for which a testing laboratory has demonstrated competence to FDA, through the application process, for conducting testing for the ASCA Pilot.

3.19 **Scope of ASCA Recognition**: list of FDA-recognized consensus standards and test methods for which an accreditation body has demonstrated competence to FDA, through the application process, for accrediting testing laboratories for the ASCA Pilot.

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3.20 **Suspending ASCA Accreditation**: putting temporary constraints in place for one or more FDA-recognized consensus standards or test methods within a testing laboratory's scope of ASCA Accreditation.

3.21 **Third-party attestation**: issue of statement, based on a decision following review, that fulfilment of specific requirements has been demonstrated

3.22 **Withdrawing accreditation**: cancelling accreditation for the full scope.

3.23 **Withdrawing ASCA Accreditation**: cancelling a testing laboratory's full scope of ASCA Accreditation

3.24 **Withdrawing ASCA Recognition**: cancelling an accreditation body's full scope of ASCA Recognition

4.0 SUBSTANCE OF THE AGREEMENT

4.1 PJLA as an ASCA recognized accreditation body is obligated to comply with the rules as outlined in the ASCA program requirements for accreditation bodies and testing laboratories.

5.0 MANUAL/ORGANIZATION

5.1 PJLA maintains a quality manual and operating procedures and work instructions to document its quality system to comply with ISO/IEC 17011. These and other related documents (including this one) state all of the requirements for (CABs) seeking accreditation under the ASCA program. PJLA will follow its organization procedures as specified in these documents in the removal, suspension or withdrawal of a (CAB's) accreditation status based on the (CAB's) failure to meet requirements of the program on an ongoing basis or at the (CAB's) request.

6.0 TRAINING AND QUALIFICATION

6.1 PJLA maintains a training, qualification and on-going continuing education program for assessors based on ASCA program requirements. Assessors are required to be trained on the following:

- The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program
- Biocompatibility Testing of Medical Devices-Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

- Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

6.2 Assessors should meet PJLA education and work experience criteria as outlined in SOP-2 Personnel Procedure. Assessors should be knowledgeable with the ASCA test methods and techniques performed by the testing laboratories.

6.3 Assessors must participate in PJLA annual refresher training or any training required by the FDA to support the ASCA program.

7.0 ASSESSMENTS AND DOCUMENTATION

7.1 PJLA will only accept application from (CABs) for tests the FDA has recognized PJLA to accredit to. If a new scope request arises that PJLA does not have recognition for an application will be submitted to the FDA for consideration.

7.2 PJLA will perform on-site assessments of (CAB's) quality systems to include their general ISO/IEC 17025 requirements, the ASCA Program Requirements for Biocompatibility Testing of Medical Device and Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment including specific testing criteria.
Each assessment will include the completion of the LF-56 2017-ASCA Checklist and Technical Assessment Matrix for each test method. All test methods must be fully assessed during initial assessments and reassessments. An assessment report will be provided to the (CAB) upon completion of the assessment. This will include a list of nonconformities detected during the visit. Depending on the severity of the nonconformity the FDA will be notified to remove the (CAB) from the program or to remove a test from the scope of accreditation. CABs will have 60 days to respond to nonconformities utilizing their internal corrective forms. Corrective action must be supported with relevant objective evidence.

7.3 Prior to the assessment, PJLA will retrieve any recent inspection findings (i.e. within 12 months) issued by the FDA for the FDA Bioresearch Monitoring Program per 21 CFR Part 58 – GLP. These will be reviewed during the on-site assessment and the assessment report will reflect the review of actions taken by the (CAB) and their continued compliance. Any findings issued in relation to the citation will documented as a PJLA finding and reported to the FDA.

7.4 During the close of the assessment (CABs) will be informed of the recommendation of the assessment.

8.0 ACCREDITATION INTERVAL/CYCLE (ASSESSMENT PROCESS)

8.1 PJLA accredits (CABs) for a two-year accreditation cycle, supplemented with yearly surveillance assessments. Initial assessments and reassessments involve a full system review of the CAB's quality management system and all tests related to the ASCA program. Scope expansions may be performed during routine assessments or separately.

9.0 CERTIFICATE PROCESS

9.1 PJLA will issue a certificate of accreditation to all CABs that have been successfully approved by PJLA's Executive Committee. Certificates will include their adherence to ISO/IEC 17025, the ASCA program requirements with the relevant tests. Accreditation for this program will only be granted for test methods recognized in the ASCA program. (CABs) may receive accreditation for tests in addition to the ASCA recognized tests. Certificates will be clearly notated to reflect ASCA and non-ASCA related tests. Upon the issuance of the scope of accreditation the CABs will be required to submit their application and scope of accreditation to the FDA for approval. Any concerns or questions regarding the certificate raised by the FDA to PJLA will be responded to immediately.

10.0 SUSPENSION/WITHDRAWAL PROCESS

10.1 PJLA will follow its suspension and withdrawal procedure (SOP-11) for all (CABs) accredited under this program. The FDA will be notified within 5 business days if a CAB is suspension or withdrawn for the accreditation program.

11.0 COMPLAINT PROCESS

11.1 PJLA will follow its Procedure for Handling Complaints SOP-9. All complaints regardless if corrective action is required, will be documented for this program and provided to the FDA as requested.

12.0 UTILIZATION OF ASCA PROGRAM ACCREDITATION REFERENCE

12.1 PJLA will ensure through the utilization of our Use of Accreditation Claim and Language Procedure (SOP-3) that CABs accredited will only make claims or statements to their accreditation of the ASCA program on relevant test reports marketing material and websites.

13.0 RECORD RETENTION (RECORDS)

13.1 PJLA currently retains records from three (3) to five (5) years (depending on the record).

14.0 PARTICIPATION AND MAINTENANCE OF RECOGNITION

14.1 PJLA will comply with the requirements of the FDA ASCA Program. This will include the following reporting, communication and compliance requirements:

- Maintain ILAC MRA Signatory Status for Testing-17025
- Verify (CABs) ability to meet 17025, ASCA program requirements and testing protocols
- Provide ASCA related program documents including assessment material to the FDA as requested
- Follow the expectations outlined in the ASCA program specifications when accredited testing CABs for the ASCA pilot.
- Allow the FDA to observe any assessment of a CAB
- Allow the FDA to observe any ILAC MRA peer evaluation
- Ensure that all relevant training is provided to assessment personnel prior to assessing any CAB
- Communicate with the FDA as necessary on program inquiries
- Notify the FDA within 5 calendar days of any relevant changes impacting our adherence to the program such as change of ILAC status, change of contact or mailing address, change of assessor capability to support the assessments
- Notify the FDA within 5 calendar days of any changes that may impact the participation of any of the testing laboratories
- Participation and attendance on teleconferences with the FDA as requested
- Provide annual updates or upon request information regarding
    - Complaint handling
    - Total number of accredited test labs with dates of accreditation
    - Number of nonconformities issued
    - Number of Suspensions Issued
    - Results of Management Review
- Maintain and amend PJLA policies based upon feedback from the FDA in order to appropriately administer the ASCA program
- Acknowledge that the accreditation for the ASCA program is based upon FDA's final approval to do so and that the FDA may withdraw ASCA recognition at any time.
- Acknowledge that material submitted for the program is submitted upon truthful and accurate information