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December 3, 2020

TO: IAS- TESTING LABORATORIES AND OTHER INTERESTED PARTIES.

SUBJECT: FDA ASCA Pilot Program – IAS Transition

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Dear Madam or Sir:

The U.S. Food and Drug Administration (FDA) has recognized IAS under the Accreditation Scheme for Conformity Assessment (ASCA) pilot program to accredit testing laboratories that perform premarket testing for medical device companies. In this program, IAS will accredit testing laboratories using the standard ISO/IEC 17025 and the ASCA program specifications.

Relying upon international conformity assessment standards and a set of FDA-identified ASCA program specifications, the pilot is intended to increase consistency and predictability in the FDA's approach to assessing conformance with FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot in medical device premarket reviews.

Ultimately, the ASCA Pilot is intended to help the FDA ensure patients have timely and continued access to safe, effective, and high-quality medical devices.

In order to participate in the program, the following steps are to be taken:

1. Obtain accreditation from an ASCA-recognized accreditation body (i.e. IAS), which includes an assessment to ISO/IEC 17025 and the ASCA Pilot program specifications.
2. For laboratories already accredited by IAS to ISO/IEC 17025, the process involves a scope expansion by IAS to include the ASCA program specifications.
3. The laboratory submittal of an application for ASCA Accreditation to the FDA.

This letter describes the methodology that will be used in order for IAS Accredited Testing Laboratories, to join the ASCA Pilot Program and achieve accreditation by IAS. This letter is also extended for Testing Laboratories that are not currently IAS Accredited for ISO/IEC 17025 but would like to become IAS Accredited for the FDA ASCA Pilot Program.

In order to understand the different scenarios, there are four case studies in the Appendix. They are as follows:

Appendix 1: A testing laboratory already accredited for ISO/IEC 17025:2017 by IAS for the FDA-recognized consensus standards for ASCA Pilot Program (no scope expansion request)

Appendix 2: A testing laboratory already accredited by IAS for ISO/IEC 17025:2017 but not for the FDA-recognized consensus standards for ASCA Pilot Program

Appendix 3: A testing laboratory that is not IAS Accredited for ISO/IEC 17025:2017 but has the FDA-recognized consensus standards for ASCA Pilot Program in their accreditation scope (Accredited by another AB)

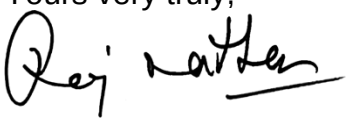
Appendix 4: A testing laboratory that is not currently accredited for ISO/IEC 17025:2017.

After successful completion of the accreditation process as described in the Appendix of this document and IAS AC89, IAS will be issuing an accreditation certificate that will include a statement of compliance to ISO/IEC 17025:2017 and FDA ASCA Pilot Program Specifications. The ASCA Pilot Scope will be listed separately in the same certificate in order to be more visible to regulators and third parties.

If you have any questions, or wish to convey your laboratories' interest in the program to IAS, please email:

- Dimitrios Katsieris, IAS Manager, dimitriosk@iasonline.org
- Prasanth Ramakrishnan, IAS Manager, Operations, Accreditation Programs, PRamakrishnan@iasonline.org
- Harry Makam, IAS Accreditation Support, hmakam@iasonline.org

Yours very truly,



Raj Nathan
President

Appendix 1

A testing laboratory already accredited for ISO/IEC 17025:2017 by IAS for the FDA-recognized consensus standards for ASCA Pilot Program (no scope expansion request)

If an IAS Accredited Testing Laboratory, already has in its scope of accreditation, FDA-recognized consensus standards for ASCA Pilot Program, IAS will be following the following policy:

a) If the lab has requested test methods from the list of Biocompatibility test methods, these will have to be demonstrated/witnessed 100% since there are additional test specific requirements specified by FDA.

b) If the lab has requested test methods from the list of Basic Safety and Essential Performance test methods, a representative sample will need to be witnessed / demonstrated to verify the competency of the lab. IAS will be accepting any witnesses already performed during the last 4 years by IAS Assessors, and will not be requiring that these methods are witnessed again.

IAS in any case will also allocate a minimum of 1 man-day in order to verify compliance of Testing Laboratories to the additional requirements of FDA for the ISO/IEC 17025 test methods and management system. This activity can be done remotely or onsite.

Appendix 2

A testing laboratory already accredited by IAS for ISO/IEC 17025:2017 but not for the FDA-recognized consensus standards for ASCA Pilot Program

Any test methods that are requested but are not in the current accreditation list, will be added after a successful scope expansion assessment process.

a) If the lab has requested any test methods from the list of Biocompatibility test methods, these will have to be demonstrated/witnessed 100%.

b) If test methods that are requested are from Basic Safety and Essential Performance test methods, a representative sample will need to be witnessed / demonstrated to verify the competency of the lab.

IAS in any case will also allocate a minimum of 1 man-day in order to verify compliance of Testing Laboratories to the additional requirements of FDA for the ISO/IEC 17025 test methods and management system. This activity can be done remotely or onsite.

Appendix 3

A testing laboratory that is not IAS Accredited for ISO/IEC 17025:2017 but has the FDA-recognized consensus standards for ASCA Pilot Program in their accreditation scope (Accredited by another AB)

In this case, IAS will need to review the last 2 assessment reports from the other AB (if 2 are performed), to recognize the number of test methods that will need to be demonstrated. This number will vary upon:

- The test methods already witnessed within the last 2 assessments.
- The level of details of the report regarding the technical demonstrations.
- If AB is signatory member of ILAC

IAS will not recognize directly any witness performed by an AB that is not FDA recognized for the ASCA Pilot Program and will need to perform an assessment based on the following requirements:

- If the lab has requested any test methods from the list of Biocompatibility test methods, these will have to be demonstrated/witnessed 100%.
- If test methods that are requested are from Basic Safety and Essential Performance test methods, a representative sample will need to be witnessed / demonstrated to verify the competency of the lab.
- IAS in any case will also allocate a minimum of 1 man-day in order to verify compliance of Testing Laboratories to the additional requirements of FDA for the ISO/IEC 17025 test methods and management system. This activity can be done remotely or onsite. If the AB is not ILAC MLA signatory, IAS will conduct a full assessment of the management system.

Appendix 4

A testing laboratory that is not currently accredited for ISO/IEC 17025:2017.

IAS will follow the normal procedure for accreditation of testing labs taking into consideration the following witness requirements:
a) If the lab has requested any test methods from the list of Biocompatibility test methods, these will have to be demonstrated/witnessed 100%.
a) If test methods that are requested are from Basic Safety and Essential Performance test methods, a representative sample will need to be witnessed / demonstrated to verify the competency of the lab.