

# PJLA Update Notification

## **Update Notification # 52**

**Update Notification Release Date:** December 10, 2020

### **Form/Procedure/Policy:**

SOP-1-Accreditation Procedure-ASCA-Rev 1.0-New

LF-56-17025-2k17-Working Document ASCA Biocompatibility-Rev 1.0 -New

LF-56-17025-2k17-Working Document ASCA Basic Safety-Rev 1.0-New

LF-56-17025-2k17-Working Document Rev 1.1

### **Attention All Applicant and Accredited Organizations:**

Below is a summary of new documents available and a modification to our current checklist for ISO/IEC 17025:2017. Please note these are not mandatory documents and are utilized as guidance tools only for laboratories.

**LF-56-17025-2k17-Working Document ASCA Biocompatibility-Rev 1.0 -New**

**LF-56-17025-2k17-Working Document ASCA Basic Safety-Rev 1.0-New**

**SOP-1-Accreditation Procedure-ASCA-Rev 1.0-New**

### **Summary:**

PJLA has developed a new standard operating procedure and 2 new checklists to support the adherence to the FDA ASCA pilot program for the accreditation of medical device testing laboratories for both basic safety and biocompatibility testing.

### **LF-56-17025-2k17-Working Document Rev 1.1**

### **Summary:**

This checklist has been updated to remove some grammatical or format issues. No major changes to the content have been made.

All checklists can be found on PJLA's website under the resource section

<https://www.pjlabs.com/resources/pjla-documents> .

Thank you!