

	DEPARTMENT OF COMMERCE National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program	ISSUE DATE: December 10, 2020
	LAB BULLETIN	NUMBER: LB-134-2020
		LAP: ECT
SUBJECT: ASCA Recognition and Release of NIST Handbook 150-11C Checklist, <i>ECT: ASCA Pilot Program – Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment</i>		

The purpose of this bulletin is to notify laboratories that NVLAP has been recognized to accredit laboratories under the FDA ASCA Pilot Program, supporting the *ASCA Accreditation* granted by the FDA to test laboratories accredited for the FDA ASCA Pilot Program specifications by an ASCA-recognized accreditation body. The background on the FDA ASCA Pilot Program can be found at the following link: <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca>.

Please note that the NVLAP accreditation which includes the FDA ASCA Pilot Program testing is the initial step in obtaining *ASCA Accreditation* from the FDA.

Notice

In response to NVLAP’s FDA ASCA Pilot Program recognition, the NIST Handbook 150-11C checklist, *ECT: ASCA Pilot Program – Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment*, based on the [*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 - Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff \(September 25, 2020\)*](#), has been created to be used by the assessors to record their review, beginning December 10, 2020.

A laboratory seeking to add the FDA ASCA Pilot Program testing to their accreditation must undergo an assessment. A laboratory may request to add this testing to their scope of accreditation by selecting the ASCA-related test methods within the NVLAP Interactive Web System (NIWS) portal. A laboratory should anticipate that the assessor review of the FDA ASCA Pilot Program specifications will increase the time and expense of an assessment.

A laboratory interested in the voluntary NVLAP ASCA Pilot Program will be required to agree to additional conditions for accreditation. In addition, the FDA could request to see ASCA Pilot Program accreditation documentation.

The NVLAP accreditation includes an assessment review covering the FDA ASCA Pilot Program specifications. The ASCA-related test methods will be noted in a specific section of the laboratory’s scope of accreditation.

After a laboratory has received NVLAP accreditation which includes the ASCA-related test methods, they may apply to the FDA for *ASCA Accreditation*.

Questions should be directed to Amanda McDonald (Amanda.McDonald@NIST.gov) and Janneth Marcelo (Janneth.Marcelo@NIST.gov).