

# FDA FACT SHEET

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## ISO/IEC 17025 ACCREDITATION COOPERATIVE AGREEMENT PROGRAM

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### Program Description

- ISO/IEC 17025 is one of the most important standards for calibration and testing laboratories, issued by the ISO (International Organization for Standardization) and the IEC (International Electrotechnical Commission).
- ISO/IEC 17025 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.
- It is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of an inspection and product certification.
- ISO/IEC 17025 is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by ISO/IEC 17025, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.
- ISO/IEC 17025 is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. ISO/IEC 17025 is not intended to be used as the basis for certification of laboratories.

### Intended Outcomes

- The goal of this cooperative agreement is for microbiological and chemical food analyses to be performed on behalf of state manufactured food regulatory programs conducted within the scope of an ISO/IEC 17025 accredited laboratory.
- The purpose is to advance the National Integrated Food Safety System (IFSS). This is accomplished by preparing the primary food testing laboratories for state manufactured food regulatory programs to achieve and maintain ISO/IEC 17025 laboratory accreditation. Laboratories will also be prepared for accreditation enhancements.
- Laboratory analyses from ISO/IEC 17025 accredited labs will increase the analytical capacity for FDA and enhance efforts to protect the food supply. Data generated by recipient laboratories is housed in eLEXNET and is used by FDA in enforcement actions, surveillance, and responses to foodborne illness outbreaks.
- Laboratory accreditation also assists state manufactured food regulatory programs in achieving conformance with the Manufactured Food Regulatory Program Standards (MFRPS).

### Program Metrics

- Current program funding: \$5.7M
- Current number of awards: 33

ISO Accreditation Awardees (FY2020)				
Alaska	Alabama	California	Colorado	Connecticut*
Florida	Georgia	Iowa	Indiana	Kansas
Kentucky	Louisiana	Massachusetts	Maryland	Michigan
Minnesota	Missouri	Mississippi	North Carolina	Nevada
New York	Ohio	Rhode Island	South Carolina	Tennessee
Texas	Virginia	Vermont	Washington	Wisconsin
West Virginia	Wyoming			

\*Note: There are 33 state lab enrollees. Connecticut has two lab agencies with ISO accreditation cooperative agreements.

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