

ISO CAP Program Updates

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Accreditation Meeting

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Program Updates

- “Original 30”
 - Laboratories entered the program in 2012
 - Cooperative agreement ends in August 2017
 - **28 of the 30 laboratories entered the “Two-Year-Bridge” CAP in 2017 for maintenance and enhancement of ISO 17025 accreditation**
 - All 28 are ISO accredited
- “New 6” in year 3
 - Laboratories entered the program in 2015
 - Cooperative agreement ends in August 2020
 - 1 of the “New 6” has achieved accreditation

Deliverables/Expectations for the Two-Year-Bridge Grantees

- Maintain current ISO/IEC 17025 accreditation
- Enhance the scope of accreditation
- Meet the minimum sample requirement of the Sample Collection and Analysis Project
- Participate in FERN activities
- Enter data into eLEXNET for data sharing (as requested by FDA)

Deliverables/Expectations for the ISO Year 3 labs

For Accredited laboratories:

- Maintain current ISO/IEC 17025 accreditation and enhance the scope of accreditation for the accredited lab
- Maintain training and PTs
- Participate in FERN activities
- Enter data into eLEXNET for data sharing
- Continue to support the sampling agreement

Deliverables/Expectations for the ISO

Year 3 labs (continued)

For laboratories seeking accreditation:

- Continue implement quality system and follow the management system policies and procedures
- Conduct at least one Internal audit and management review to identify non-conformances
- Develop an improvement plan to address each non-conformance
- PT plan and requirements
- Training
- Gap analysis
- FERN
- eLEXNET
- Sampling agreement

ISO Lab samples conducted under Sampling Agreement – FY17

Program	# of Labs	Total # Samples analyzed	Sampling range
MFRPS	34	11156	13-2600

