

# 2018 APHL™ ANNUAL MEETING

and twelfth government environmental laboratory conference

June 2-5, 2018  
Pasadena, CA  
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**#aphl**



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## Costs Associated with Accreditation: Laboratory Survey

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# Sustainability, that is the question!

- FDA has been supporting laboratory accreditation efforts for the past six years.
  - Continued funding is not guaranteed.
- Many laboratories recognize that sustaining their ISO/IEC 17025 accreditation in the absence of federal funding would be difficult.

**How much does ISO/IEC 17025  
accreditation cost?**

# Are all accreditation-related laboratory costs equal?

- Costs can vary from laboratory to laboratory, depending on:
  - Size
  - Starting point
  - Staffing
  - Location
  - Testing methods on scope
- APHL conducted a survey of accredited laboratories participating in FDA's cooperative agreements to determine approximate costs.

# Assessment Methods



# Fielding the Survey

- Assessment tool was beta-tested and fielded in July 2017 to 30 accredited laboratories involved in the:
  - FDA ISO cooperative agreement
  - FDA AFRPS cooperative agreement

Note: Survey was also fielded to two laboratories receiving assistance from an APHL consultant through the FDA Associations Cooperative Agreement
- APHL instructed respondents to include only those costs directly related to their pursuit and/or maintenance of ISO/IEC 17025 accreditation.
- 18 of 30 laboratories responded (60%)



# Results and Analysis



# General Information

Laboratory Identifier	Full-time Employees (Technical)	Years Accredited to ISO/IEC 17025	Human Food		Animal Food	
			Samples Per Year	Testing Methods on Scope	Samples Per Year	Testing Methods on Scope



# ISO/IEC 17025 Assessment Fees

- Accrediting bodies assess laboratory conformance to the ISO standard.
  - Assessment Fee
  - Auditor's travel expenses.
- There is an initial assessment fee upon application for accreditation, with either a yearly or bi-yearly fee for reassessment.
- Having more on scope methods on scope—or having more than one scope (i.e. microbiology and chemistry)—equates to more time the auditor spends in the laboratory.

**Median: \$7,250 (initial); \$6,000 (post-initial)**

**Range: \$1,300 - \$16,518 (initial); \$1,300 - \$17,201 (post-initial)**

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# Calibration Costs

- All laboratories are required to calibrate their instruments and equipment used during testing.
- Some labs choose to perform this calibration testing in house, while others contract out the work to ISO-certified third party vendors.
- Each of these methods comes at significant cost.
- Many labs reported high costs for the calibration of pipettes, reference temperature data loggers, thermometers and thermocouples, and balances.

**Median: \$10,927**

**Range: \$1,241 - \$41,650**

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# Preventive Maintenance Costs

- The frequency with which the laboratory must perform preventive maintenance may have increased due to ISO/IEC 17025.
- Typically, service contracts on chemistry equipment is about 10% of the purchase price
- Various factors influence the costs reported, including contracts in place prior to ISO/IEC 17025 accreditation, preventive maintenance performed in-house, and the number of instruments and equipment used for in scope methods.

Median: \$60,788

Range: \$0 - \$300,857

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# Proficiency Testing Costs

- Participating in proficiency testing programs comes with a cost.
- Some accreditation body requiring that the laboratory pass at least one proficiency test per method, test type, or technology on their scope per year
  - More methods on scope = more proficiency test samples needed per year.

**Median: \$3,327**

**Range: \$0 - \$9,000**

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# Software and/or Monitoring System Costs

- These included document control software, laboratory information management systems, and temperature monitoring systems.
  - Highest costs attributed to purchase of LIMS software (\$100,00 - \$450,000)
  - Annual maintenance cost is also several thousand dollars.
- Some laboratories already had these systems in place prior to pursuing accreditation. Others developed items in-house utilizing available platforms (i.e. SharePoint, Microsoft, etc.).
- While these systems are not required to meet the ISO/IEC 17025 standard, many laboratories choose to purchase these expensive items to ease daily operations.

Median: \$44,627

Range: \$0 - \$460,000

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**Median accreditation-related  
laboratory cost: \$311, 485**

**Range: \$67,000 - \$1.35 million**

# Discussion



# Data Limitations

- It is possible that some laboratories answered questions with a different perspective than others.
- Several respondents found it difficult to separate which policies the laboratory instituted due to accreditation and which are just “the cost of doing business.”
- Some laboratory costs (i.e. laboratory security systems) were for the entire laboratory.
- Laboratories surveyed were receiving federal funding for accreditation.

# Overall costs

- Accreditation costs seem to be highly dependent on several factors, such as location, size, and accreditation scope.
- The most important factor is what policies, procedures, equipment and software the laboratory had in place prior to seeking accreditation.

# Conclusions

- ISO/IEC 17025 accreditation provides the foundation for laboratories to generate defensible data that can be shared between food safety agencies.
- Reported costs are significant, and some laboratories may not be financially able to sustain their accreditation without federal funding.



FDA's investment in ISO/IEC 17025 accreditation for state human and animal food laboratories will **improve** food safety and **advance** public health.

# Acknowledgements

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- FDA ORA/OP

# Questions?

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<https://www.aphl.org/aboutAPHL/publications/Documents/FS-2018Feb-ISO-IEC-Accreditation-Costs-Survey-Report.pdf>