2018 APHL ANNUAL MEETING

and twelfth government environmental laboratory conference

June 2-5, 2018
Pasadena, CA
Pasadena Convention Center

#aphl
Costs Associated with Accreditation: Laboratory Survey
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June 4, 2018
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

<table>
<thead>
<tr>
<th>Laboratory Identifier</th>
<th>Full-time Employees (Technical)</th>
<th>Years Accredited to ISO/IEC 17025</th>
<th>Human Food</th>
<th>Animal Food</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Samples Per Year</td>
<td>Testing Methods on Scope</td>
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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)
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
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
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
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 ($100,000 - $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
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

• APHL’s Food & Feed Testing Subcommittee
• APHL Food Safety Program
• APHL Institutional Research Program
• FDA ORA/ORS
• FDA ORA/OP
Questions?

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