

Laboratory Costs of ISO/IEC 17025 Accreditation: A 2017 Survey Report



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Background

The US Food and Drug Administration (FDA) has identified laboratory accreditation as a critical element for ensuring the integrity of human and animal food testing. Such data integrity is necessary to support mutual reliance, i.e. trust and use of data shared between food safety agencies (federal, state, local and tribal). Accreditation to an international standard, such as ISO/IEC 17025, is one step towards data defensibility.

Before FDA implemented the ISO cooperative agreement program, there were less than 25 accredited governmental food testing laboratories, including state, local and federal laboratories. In 2012, FDA provided five-year cooperative agreements to 31 state laboratories that perform testing for the Manufactured Food Regulatory Program Standards (MFRPS) to achieve (23 laboratories) or enhance (eight laboratories) ISO/IEC 17025 laboratory accreditation. In 2015, an additional six food testing and 20 animal food testing laboratories were awarded five-year cooperative agreements to advance their efforts towards accreditation through conformance to MFRPS and the Animal Food Regulatory Program Standards (AFRPS), respectively; one more animal food laboratory was funded in 2016, and two more were added in 2017. Additionally, to assist the laboratories in their accreditation efforts, FDA also awarded a five-year cooperative agreement to the Association of Public Health Laboratories (APHL), the Association of Food and Drug Officials (AFDO) and the Association of American Feed Control Officials (AAFCO). As part of this cooperative agreement, APHL provided direct technical assistance via an accreditation consultant to laboratories identified by FDA as having a proven commitment to seeking ISO/IEC 17025 accreditation but who were not participating in the FDA ISO cooperative agreement program.

Many laboratories recognize that sustaining their ISO/IEC 17025 accreditation in the absence of federal funding will be difficult. The costs of accreditation can vary from laboratory to laboratory, depending on the size, starting point, staffing, location, and testing methods of the laboratory. Costs can include preventive maintenance contracts, assessment fees, training, and staff. APHL conducted a survey of many of the laboratories participating in FDA's ISO cooperative agreement program and those receiving technical assistance through APHL to gain a better understanding of the approximate costs associated with becoming and maintaining ISO/IEC 17025 accreditation. This information can help inform future funding models and allow additional laboratories to plan and prepare for accreditation moving forward.

Assessment Methods

APHL convened a group of members to develop an assessment tool that was beta-tested by two laboratories in March 2017. The survey was fielded in July 2017 to 30 accredited laboratories involved in the FDA ISO Cooperative Agreement, the FDA AFRPS Cooperative Agreement, and accredited laboratories that received assistance from an APHL consultant through the FDA Associations Cooperative Agreement. APHL instructed respondents to include only those costs that directly relate to their pursuit and/or maintenance of ISO/IEC 17025 accreditation.

Of 30 survey recipients, 18 laboratories responded (60%); twelve laboratories had been accredited for two years or less. Each laboratory was assigned a number to preserve anonymity.

Results and Analysis

The following tables present the data gathered from the survey. If a laboratory did not report any costs associated with a particular category, no amount was entered in the table and it was not calculated into the median laboratory cost. If a laboratory reported \$0.00 costs for a category, this amount was included in the table and was calculated into the median laboratory cost.

General Information

The survey captured information regarding laboratory staffing, sample volume, and in-scope testing methods to provide context for the associated costs reported from respondents (Table 1).

Table 1. General Laboratory Respondent 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
1	9	2	777	10	0	0
2	59	6	1558	29	1364	9
3	10	1	2000	4	700	4
4	4	1	740	16	0	0
5	4	1.5	172	19	0	0
6	14	10	10000	21	200	1
7	19	10	9510	44	0	0
8	7	2	0	0	611	8
9	5	2	700	9	0	0
10	9	1.5	0	15	0	0
11	3	5	5623	17	693	10
12	4	<1	469	5	20	0
13	15	7	480	6	580	13
14	7	7	5000	5	1000	3
15	12	<1	100	5	1500	1
16	8	<1	1739	5	2449	2
17	21	9	19715	17	497	7
18	15	2	385	6	2100	1

ISO/IEC 17025 Training Costs

Continuing education and training are an important aspect of maintaining accreditation to the ISO/IEC 17025 standard, as is demonstrating competency in performing calibration or testing services. Continuing education and training requirements are mandatory for maintaining ISO/IEC 17025 accreditation. Table 2 shows respondents' annual costs for technical and ISO-related trainings.

Table 2. ISO/IEC 17025 Accreditation Training Costs

Laboratory Identifier	Full-time Employees (Technical Staff Only)	ISO/IEC 17025 Training Costs
1	9	\$ 8,621.00
2	59	\$ 24,600.00
3	10	\$ 3,000.00
4	4	\$ 3,000.00
5	4	\$ 18,491.00
6	14	\$ 13,000.00
7	19	\$ 18,000.00
8	7	\$ 2,500.00
9	5	\$ 12,430.00
10	9	\$ 0.00
11	3	\$ 25,000.00
12	4	\$ 5,875.00
13	15	\$ 6,000.00
14	7	\$ 7,000.00
15	12	\$ 13,500.00
16	8	\$ 22,000.00
17	21	\$ 155,600.00
18	15	\$ 67,000.00

Median: \$12,715**Range: \$0 - \$155,600**

The median cost for ISO/IEC 17025 accreditation-related training was \$12,715. The laboratory reporting no costs related to training indicated that it performed this training in-house; therefore, they stated no direct cost. One laboratory reported spending \$155,600 on training. They spent \$60,600 on ISO training over 10 years, investing on an “as needed” basis with intense ISO training at the start of accreditation and a refresher course in 2016. The laboratory also spent \$95,000 since 2012 on various trainings, including workshops, on-site trainings, and web training that included access to recorded sessions. The cost included all travel expenses (when applicable) and training registration.

ISO/IEC 17025 Assessment Fees

Laboratories contract with an accrediting body to assess their conformance to the ISO/IEC 17025. These accrediting bodies charge a fee for their auditors to assess the laboratory against the requirements in the ISO/IEC 17025 standard, as well as for the auditor’s travel expenses during the on-site visit to the laboratory. The laboratory pays an initial assessment fee when they first apply for accreditation, and pay either a yearly or bi-yearly fee for reassessment (this varies by accrediting body). Table 3 lists the initial and renewal assessment fees for respondent laboratories.

Table 3. ISO/IEC 17025 Accreditation Assessment Fees

Laboratory Identifier	Initial Assessment Fees	Renewal Assessment Fees	Number of Human Food Testing Methods On Scope	Number of Animal Food Testing Methods On Scope
1	\$ 7,500.00	\$ 2,300.00	10	0
2	\$ 16,330.00	\$ 8,483.33	29	9
3	\$ 8,000.00	\$ 6,000.00	4	4
4		\$ 4,200.00	16	0
5	\$ 10,000.00	\$ 7,500.00	19	0
6		\$ 6,000.00	21	1
7	\$ 16,518.00	\$ 6,925.00	44	0
8	\$ 1,300.00	\$ 1,300.00	0	8
9	\$ 14,000.00	\$ 7,000.00	9	0
10	\$ 8,400.00	\$ 6,100.00	15	0
11		\$ 17,201.00	17	10
12	\$ 8,570.00	\$ 8,570.00	5	0
13		\$ 4,500.00	6	13
14	\$ 7,000.00	\$ 5,000.00	5	3
15	\$ 8,500.00	\$ 6,000.00	5	1
16	\$ 7,000.00	\$ 4,000.00	5	2
17	\$ 6,800.00	\$ 13,955.00	17	7
18	\$ 4,000.00	\$ 4,100.00	6	1

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

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

The median cost of laboratories' initial assessment fees was \$7,250, although they ranged from \$1,300 to \$16,518. Those laboratories that did not report an initial assessment fee have been accredited for 5 or more years and likely did not have records of their initial assessment fee readily available for this survey. The median cost of renewal assessment fees was \$6,000, with costs ranging from \$1,300 to \$17,201. The largest variation in cost is due to the number of methods the laboratory has on their scope of accreditation. The more methods that a laboratory has on scope or the number of scopes (i.e., microbiology and chemistry), the more time the auditor(s) must spend at the facility. The locality of the laboratory, auditor(s) travel costs and the chosen accrediting body may also factor into the assessment costs.

Consultant Costs

Some laboratories choose to hire a consultant to aid in the accreditation process. The consultant can help ensure that the laboratory has all necessary elements in place prior to applying for accreditation. There are many reasons why a laboratory may choose to hire a consultant, including lack of experience with the ISO standard or lack of staff able to devote their time to the accreditation process. Table 4 shows the amount respondents spent on accreditation consultants.

Table 4. ISO/IEC 17025 Accreditation Consultant Costs

Laboratory Identifier	Accreditation Consultant Costs
1	\$ 0.00
2	
3	\$ 10,000.00
4	\$ 0.00
5	\$ 4,905.00
6	\$ 3,000.00
7	\$ 0.00
8	\$ 0.00
9	\$ 0.00
10	\$ 0.00
11	\$ 0.00
12	\$ 16,500.00
13	
14	\$ 10,000.00
15	
16	\$ 25,000.00
17	\$ 14,400.00
18	\$ 35,500.00

Median: \$3,000**Range: \$0 - \$35,500**

The median laboratory cost for an ISO/IEC 17025 accreditation consultant was \$3,000. One laboratory spent \$35,500 on pre-assessment consulting work. While this cost is not applicable to all laboratories, it can be critically important for some laboratories in order to achieve accreditation in a timely manner. Some laboratories utilized the expertise of APHL's Accreditation Consultant, who performed a laboratory gap analysis, reviewed documents and quality manuals, and provided guidance throughout the accreditation process at no cost to the laboratory. However, the Accreditation Consultant is available only through federal funding and may not always be an option.

Purchase of Supplies and Equipment

Many laboratories must purchase new or certified supplies or equipment on their journey to ISO/IEC 17025 accreditation. Equipment can include (but are not limited to) certified thermometers, certified weights, certified timers, reference standards and cultures, water testing systems, and temperature data loggers. Table 5 shows annual costs for respondents' supply and equipment purchases.

Table 5. Purchase of Supplies and Equipment

Laboratory Identifier	Purchase of Supplies and Equipment
1	\$ 44,486.00
2	\$ 15,750.00
3	\$ 3,800.00
4	\$ 26,350.00
5	\$ 18,689.00
6	\$ 17,100.00
7	\$ 100.00
8	
9	\$ 5,200.00
10	\$ 7,870.00
11	\$ 10,000.00
12	\$ 7,030.00
13	\$ 49,576.87
14	\$ 15,000.00
15	\$ 15,300.00
16	\$ 4,000.00
17	\$ 81,748.00
18	\$ 24,712.00

Median: \$15,300**Range: \$100 - \$49,576**

The median annual cost of supply and equipment purchases was \$15,300, ranging from \$100 to \$49,576. Laboratory #7 reported spending only \$100 on two certified thermometers per year; other equipment was either not used or not purchased specifically due to ISO/IEC 17025 accreditation (Laboratory 7 has been accredited for 10 years). Laboratory 13 reported a high annual cost for certified reference materials (\$45,324). All pesticide, feed, fertilizer and ground water methods are under Laboratory 13's accreditation scope, and the pesticide standards—they analyze samples for over 1,000 pesticides—are very expensive. The standard requires the use of ISO/IEC 17025 certified reference standards and reference materials for use as method calibration standards, Laboratory Control Samples (LCS) and certified blank material. More methods on a laboratory's scope equates to higher costs for certified reference standards and reference materials. All reference materials must be traceable to SI units of measurements or to certified reference materials.

Calibrations

Calibration is the comparison of a measured value obtained by equipment (or instrument) with those of a standard with known accuracy. All laboratories are required to calibrate their instruments and equipment used during testing. Some laboratories choose to perform this calibration testing in-house, while others contract the work (often due to staffing or the time required for this work) to third party vendors (who are also ISO/IEC 17025 certified). Each of these methods comes at significant cost, as shown in Table 6 below.

Table 6. Calibration Costs

Laboratory Identifier	Calibration Costs
1	\$ 1,241.00
2	\$ 34,000.00
3	\$ 10,000.00
4	\$ 10,927.50
5	\$ 18,753.78
6	\$ 9,900.00
7	\$ 8,890.00
8	
9	\$ 345.00
10	\$ 4,518.00
11	\$ 16,071.00
12	\$ 2,352.00
13	\$ 14,744.84
14	\$ 11,000.00
15	\$ 11,500.00
16	\$ 41,650.00
17	\$ 41,585.00
18	\$ 4,385.00

Median: \$10,927**Range: \$1,241 - \$41,650**

The median cost of calibrations was \$10,927. Laboratory 9 reported that they had a contract in place to calibrate their balances prior to becoming ISO/IEC 17025 accredited, but the contract increased by \$345 after accreditation due to their accrediting body's requirement for including measurement uncertainty. Many of the laboratories reported high costs for the calibration of pipettes, reference temperature data loggers, thermometer/thermocouples, and balances. Some laboratories reported purchasing temperature monitoring systems rather than verifying thermometers; typically, the calibrations for these systems are part of a service contract by a company or manufacturer.

Preventive Maintenance

Preventive maintenance is a requirement under ISO/IEC 17025 aimed at preventing the failure of equipment before it actually occurs. By replacing worn parts before they fail, it increases the likelihood that equipment or instrumentation are performing reliably. Some preventive maintenance can be performed in-house, but often it requires a service contract with the vendor, especially with proprietary instrumentation; these service contracts can be costly. While laboratories may have been performing preventive maintenance on their equipment prior to accreditation, the frequency with which the laboratory must perform preventive maintenance may have increased due to ISO/IEC 17025 accreditation and is therefore a cost-factor. Table 7 below lists respondents' preventive maintenance costs.

Table 7. Preventive Maintenance Costs

Laboratory Identifier	Preventive Maintenance Costs
1	\$ 5,500.00
2	\$ 300,857.00
3	\$ 33,000.00
4	\$ 50,000.00
5	\$ 40,608.00
6	\$ 122,000.00
7	\$ 0.00
8	
9	\$ 0.00
10	\$ 3,000.00
11	\$ 172,033.00
12	\$ 32,220.00
13	\$ 60,778.06
14	\$ 71,750.00
15	\$ 105,000.00
16	\$ 64,500.00
17	\$ 278,476.00
18	\$ 70,331.00

Median: \$60,788**Range: \$0 - \$300,857**

The median cost of preventive maintenance was \$60,788, with prices ranging from \$0 to \$300,857. One of the laboratories that reported no cost indicated that preventive maintenance costs were not directly related to their ISO/IEC 17025 accreditation and therefore were not included in the survey. Laboratory #2 reported \$83,395 in preventive maintenance contracts for microbiology equipment as well as \$217,462 in contracts for chemistry equipment. Preventive maintenance for chemistry equipment can greatly increase costs. Typically, service contracts on chemistry equipment is about 10% of the purchase price; a service contract on a \$300,000 gas chromatography/mass spectrometry (GC/MS) instrument can cost about \$30,000 per year for preventive maintenance and service.

Various factors influence the costs reported, including contracts the laboratory had in place prior to ISO/IEC 17025 accreditation, preventive maintenance performed in-house, and the number of instruments and equipment in the laboratory used for in scope methods that require preventive maintenance.

Proficiency Testing Due to Accreditation

Proficiency testing determines the performance and competency of a laboratory for specific tests or measurements. The laboratory's results are compared with those of its peers and statistical analyses are performed to determine these parameters. All laboratories accredited to the ISO/IEC 17025 standard are required to assure the quality of test results, and this usually includes the participation of inter-laboratory comparison or proficiency testing programs (which are also encouraged to be accredited to the ISO 17043 standard). Participating in these proficiency testing programs comes with a cost, which are listed in Table 8.

Table 8. Proficiency Testing Costs Due to ISO/IEC 17025 Accreditation

Laboratory Identifier	Number of Human Food Testing Methods On Scope	Number of Animal Food Testing Methods On Scope	Proficiency Testing Costs Due to ISO/IEC 17025 Accreditation
1	10	0	\$ 5,416.00
2	29	9	\$ 2,131.00
3	4	4	\$ 0.00
4	16	0	\$ 0.00
5	19	0	
6	21	1	\$ 1,500.00
7	44	0	\$ 6,000.00
8	0	8	
9	9	0	\$ 0.00
10	15	0	\$ 0.00
11	17	10	\$ 3,255.00
12	5	0	\$ 6,010.00
13	6	13	\$ 3,400.00
14	5	3	\$ 4,500.00
15	5	1	\$ 8,500.00
16	5	2	\$ 9,000.00
17	17	7	\$ 5,500.00
18	6	1	\$ 1,425.00

Median: \$3,327**Range: \$0 - \$9,000**

The median cost of proficiency tests implemented specifically due to accreditation was \$3,327. Four laboratories reported no cost due to additional proficiency tests, with most indicating that while they participate in proficiency testing programs for human and animal food testing, there were no additional costs specifically due to accreditation. FDA and the US Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) Food Emergency Response Network (FERN) programs are proficiency testing providers that do not charge a fee for their samples, so laboratories may utilize these samples if they participate in FERN (funded or unfunded). Laboratory #16 reported \$9,000 in proficiency tests, the highest of all respondents. With some accreditation body requiring that the laboratory pass at least one proficiency test per method, test type, or technology on their scope per year, the more methods a laboratory has on their scope, the more proficiency test samples may be needed per year.

Software and Monitoring Systems

Respondents were asked to document costs due to the purchase, development and/or maintenance of various software or monitoring systems. These included document control software, laboratory information management systems (LIMS) and temperature monitoring systems. These costs were combined with the costs of control chart and audit to calculate a total software and monitoring system cost, as shown in Table 9.

Table 9. Software and/or Monitoring System Costs

Laboratory Identifier	Document Control Software	Laboratory Information Management System (LIMS)	Control Charting Software	Audit Software	Temperature Monitoring System	Total Software and/or Systems Cost
1	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
2	\$25,000.00				\$47,000.00	\$ 80,000.00
3				\$ 200.00	\$ 500.00	\$ 700.00
4	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
5	\$ 6,736.00		\$ 806.00			\$ 7,542.00
6		\$ 31,000.00				\$149,000.00
7	\$12,000.00	\$ 67,500.00	\$ 50.00	\$ 0.00	\$ 7,500.00	\$ 87,050.00
8	\$ 0.00	\$ 17,000.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 17,000.00
9	\$50,000.00	\$ 0.00	\$ 185.00	\$ 0.00	\$ 0.00	\$ 50,185.00
10	\$ 4,400.00		\$ 0.00	\$ 0.00		\$ 4,400.00
11	\$21,199.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 21,199.00
12	\$16,089.00	\$ 9,780.00			\$13,200.00	\$ 39,069.00
13		\$ 250,000.00			\$50,000.00	\$300,000.00
14		\$ 110,000.00			\$25,000.00	\$ 31,000.00
15		\$ 4,500.00				\$ 4,500.00
16	\$15,000.00	\$ 20,000.00	\$ 5,000.00		\$20,000.00	\$ 60,000.00
17		\$ 450,000.00			\$10,000.00	\$460,000.00
18		\$ 95,051.00			\$12,500.00	\$107,551.00

Median: \$44,627**Range: \$0 - \$460,000**

The median total software and/or system cost was \$44,627, with a broad range from \$0 to \$460,000. Most of the higher costs were attributed to the purchase of LIMS software, which ranged from \$95,051 to \$450,000; the annual maintenance cost of the LIMS software is also several thousand dollars. The median cost of temperature monitoring systems was \$8,750 with Laboratory #13 reporting a purchase price of \$50,000. Several laboratories reported low costs because their laboratories already had these systems in place before pursuing ISO/IEC 17025 accreditation. Some laboratories developed some items in-house, such as document control software and control charting software, utilizing platforms already available to the laboratory (i.e. SharePoint, Microsoft Excel, Microsoft Access, etc.), but these may require someone in-house with expertise to help build these systems.

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. Oftentimes, the software can solve problems associated with human errors, especially in document control. Temperature monitoring systems can provide real-time temperatures of equipment, with emails to laboratory staff during the workday and after hours to protect sample integrity, and laboratories can detect trends which may lead to sooner maintenance on a refrigerator, for example, before a costly failure occurs and reagents and samples are affected. Additionally, prior to implementing a temperature monitoring system, temperatures are recorded manually, often two times per day or more, and for many pieces of equipment in a large laboratory.

Salaries Due to ISO/IEC 17025 Accreditation

Becoming accredited to the ISO/IEC 17025 standard requires time, money and resources. Many laboratories hire more staff to offset the work due to accreditation. These staff can be technicians or administrative staff, but are oftentimes dedicated quality staff. Many laboratories utilized the federal funding in the ISO Cooperative Agreements to pay for full-time or part-time Quality Managers. Table 10 below shows salary costs of additional staffing needs to earn and/or maintain accreditation.

Table 10. Annual Salaries Due to ISO/IEC 17025 Accreditation

Laboratory Identifier	Annual Salaries Due to ISO/IEC 17025 Accreditation
1	\$ 181,113.00
2	\$ 200,000.00
3	\$ 45,000.00
4	\$ 199,069.00
5	\$ 170,000.00
6	\$ 110,000.00
7	\$ 183,000.00
8	\$ 45,000.00
9	\$ 0.00
10	\$ 87,000.00
11	\$ 168,000.00
12	\$ 119,343.00
13	\$ 56,340.00
14	\$ 175,000.00
15	\$ 12,000.00
16	\$ 160,000.00
17	\$ 300,000.00
18	\$ 442,697.00

Median: \$164,000

Range: \$0 - \$442,697

Median salary costs were \$164,000. One laboratory (Laboratory #9) reported no additional salary costs due to accreditation, presumably because the laboratory did not hire additional staff. Laboratory #18 reported the highest annual salary costs (\$442,697), which accounts for the full-time and part-time personnel assigned to accreditation activities, including QA managers, deputy QA managers and chemists—and partial time spent by other full-time management and administrative personnel. Some laboratories hire staff that are dedicated to quality assurance activities, while others spread those activities out across multiple laboratory staff.

Total Annual Cost of ISO/IEC 17025 Accreditation

Based on all of the costs listed above, Table 11 lists the cumulative annual costs for each laboratory that are directly related to becoming accredited to the ISO/IEC 17025 standard.

Table 11. Total Annual Costs Due to ISO/IEC 17025 Accreditation

Laboratory Identifier	Total Annual Costs Due to ISO/IEC 17025 Accreditation	Full-time Employees (Technical Staff Only)	Years Accredited to ISO/IEC 17025	Human Food		Animal Food	
				Samples Per Year	Testing Methods on Scope	Samples Per Year	Testing Methods on Scope
1	\$ 256,177.00	9	2	777	10	0	0
2	\$ 682,151.33	59	6	1558	29	1364	9
3	\$ 119,500.00	10	1	2000	4	700	4
4	\$ 293,546.50	4	1	740	16	0	0
5	\$ 296,488.78	4	1.5	172	19	0	0
6	\$ 431,500.00	14	10	10000	21	200	1
7	\$ 326,483.00	19	10	9510	44	0	0
8	\$ 67,100.00	7	2	0	0	611	8
9	\$ 89,160.00	5	2	700	9	0	0
10	\$ 121,288.00	9	1.5	0	15	0	0
11	\$ 432,759.00	3	5	5623	17	693	10
12	\$ 245,539.00	4	<1	469	5	20	0
13	\$ 495,339.77	15	7	480	6	580	13
14	\$ 337,250.00	7	7	5000	5	1000	3
15	\$ 184,800.00	12	<1	100	5	1500	1
16	\$ 397,150.00	8	<1	1739	5	2449	2
17	\$1,358,064.00	21	9	19715	17	497	7
18	\$ 726,201.00	15	2	385	6	2100	1

Median: \$311,485

Range: \$67,000 - \$1,358,064

The median laboratory cost due to ISO/IEC 17025 accreditation was \$311,485, although single laboratory costs ranged from \$67,100 to \$1,358,064. Referring to the factors (i.e. laboratory size, samples per year, years accredited, etc.) listed in Table 11 may provide context for these accreditation costs.

Discussion

Data Limitations

The data provide a detailed overview of the laboratory costs associated with ISO/IEC 17025 accreditation. While all respondents were provided with the same set of survey instructions, it is possible that some laboratories answered questions with a different perspective than others. Several respondents, particularly those who have been accredited for a number of years, reportedly found it difficult to separate what policies the laboratory instituted due to ISO/IEC 17025 accreditation (and therefore should be reported as a cost) and what policies are just the “cost of doing business.” Some laboratories reported that some of the costs, such as laboratory security systems, were for the entire laboratory and not just the human and/or animal food sections. It is also important to consider that the majority of laboratories surveyed were receiving federal funding specifically for ISO/IEC 17025 accreditation and may have higher reported costs because of the availability of those federal monies. These caveats are important to consider when reviewing the data.

Overall ISO/IEC 17025 Accreditation Costs

As the data show, attaining accreditation to the ISO/IEC 17025 standard is a costly endeavor. It is a serious undertaking that may cost hundreds of thousands of dollars. Accreditation costs are highly dependent on several factors, including laboratory location, size and accreditation scope (i.e., number of tests under the scope), among others. While the cost can seem like a daunting number, it is interesting to note that the laboratory may mitigate accreditation costs if several sections or programs requiring accreditation share the costs. For example, one laboratory shares the cost of their LIMS and document control software with their Food Safety Inspections unit. Some costs are large, one-time purchases of software or equipment. Others are not required for accreditation but automate many of the laboratory processes to prevent errors and/or provide data useful to laboratory operations, such as document control software and automated temperature monitoring devices. The annual maintenance fees following those purchases, while still significant, are considerably less expensive.

Laboratory location can be a key factor in accreditation costs, especially when considering salaries for quality assurance staff. A laboratory in California or New York will likely have higher salary costs than a laboratory in South Dakota or Montana. Similarly, auditor travel costs during assessments can vary, as per diem varies from region to region. In addition, this travel cost would vary depending on the number of methods and disciplines on-scope, with multiple scopes often requiring two auditors instead of one.

The most important factor when determining the cost of ISO/IEC 17025 accreditation is what policies, procedures, equipment and software the laboratory had in place prior to deciding to pursue the accreditation. If the laboratory had previously purchased a LIMS system, that could equate to a \$250,000 cost savings. If the laboratory already had a full-time quality manager in the laboratory, that eliminates another cost. If the laboratory was previously calibrating their equipment (pipettes, balances, centrifuges, etc.) according to the ISO/IEC 17025-mandated schedule, these were not additional expenses. Having a strong quality management system in place prior to pursuing ISO/IEC 17025 accreditation can reduce laboratory costs. For more information on key components of a quality management system, please refer to the checklist available in Appendix A of [Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories](#).

A laboratory should be performing maintenance on their instruments, but perhaps the interval at which that maintenance is performed—and therefore, the cost—increases with accreditation. A laboratory may have had pipettes or thermometers calibrated by an outside company, but with accreditation, that company must be also accredited to ISO/IEC 17025 (if possible). Their cost for providing this service under their scope of accreditation may be passed on to the customer.

Conclusion

FDA has provided over \$50 million over the past five years in support of human and animal food testing laboratories working towards attaining or expanding their scope of ISO/IEC 17025 accreditation. Success stories involving state laboratories awarded with the FDA ISO Cooperative Agreement, the FDA Animal Food Regulatory Standards (AFRPS) Cooperative Agreement or who received assistance from an APHL consultant through the FDA Associations Cooperative Agreement, are the proof of the return on investment in ISO/IEC 17025 accreditation. Because of the data generated by these laboratories, contaminated food and feed were recalled at state or nationwide levels. In some instances, a product was removed from shelves before known cases of human illness. In others, laboratory results were the key element to link contaminated food with human illness.

As food safety regulatory programs continue to expand and receive support by federal agencies, laboratory-specific programs such as the ISO Cooperative Agreements should be coordinated with regulatory programs and receive similar, ongoing federal support. The ISO/IEC 17025 standard provides the foundation for laboratories to generate defensible data that can be shared between food safety agencies. Laboratories accredited to the ISO/IEC 17025 standard are essential for a nationally integrated food safety system but without federal support, states may not be financially able to support its implementation and maintenance.

The costs reported in this survey are significant, and some laboratories may not be financially able to sustain their ISO/IEC 17025 accreditation in the absence of federal funding. Sustaining laboratory accreditation supports the Food Safety Modernization Act's aim of creating a prevention-based food safety system. By facilitating long-term, permanent improvements to our nation's laboratory network, FDA's investment in ISO/IEC 17025 accreditation for state human and animal food testing laboratories will advance public health initiatives and improve the safety of the US food supply.

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Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
Phone: 240.485.2745
Fax: 240.485.2700
www.aphl.org