National Cooperation for Laboratory Accreditation

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Reliable Results through Recognized Accreditation

Comments

submitted electronically to

The US Department of Health and Human Services

Food and Drug Administration

on

Public Law 111 - 353

"FDA Food Safety Modernization Act"

Economic Costs for Recognition

Additional Information Submitted Subsequent to April 28, 2011 Comments from NACLA

This additional report is submitted to the US Food and Drug Administration (FDA) in support of Public Law 111 – 353, "FDA Food Safety Modernization Act" (FSMA).

Costs Associated Using NACLA Model Fees for Recognition in 2011

As part of the FDA's consideration, NACLA is submitting information on the costs involved in the current recognition process.

- Application fee for recognition:
  - $1,500 – NACLA members
  - $3,000 – non-NACLA members
- Lead Evaluator cost to accreditation body (AB):
  - $750/day
- Evaluation Team member cost to AB: $250 per day per person for additional evaluation team

The AB reimburses the costs of travel, lodging, meals and other legitimate expenses of the team members. Where possible, NACLA works to keep those costs controlled by using evaluation team personnel who may be regional.

A list of the NACLA evaluation procedure steps is listed in Appendix I attached. Using estimated data for Example 2, one possible NACLA fee scenario for a NACLA member organization:

CATEGORY	COST PER DAY	TOTAL COST
Recognition Application Fees – basic + one additional sector specific		$1,500
Lead Evaluator – pre-visit preparation, on-site visit, document review, report writing, post evaluation document review @ 10 days total for all work	$750	$7,500
Evaluation Team – One (1) member – six days	$250	$1,500
Evaluation Team – other members – four days total	$250	$1,000
Total Evaluation Process Cost to AB in This Scenario		**$11,000**

It should be restated here that NACLA is a recognition organization that is domestic and does not focus outside of the United States. This domestic focus allows NACLA to use US evaluation team members to evaluate US operations.

Background on NACLA

Located in Washington, DC, NACLA is a not-for-profit corporation established in 1998. It was founded by representatives of public and private-sector organizations to provide coordination and focus

interested in laboratory accreditation. NACLA is a stakeholder organization. Accordingly, its leadership body (the Board of Directors/Operations Council) is comprised of balanced representation from the four key stakeholder groups: Industry, Government, Laboratories and Accreditation Bodies. NACLA's stakeholders work toward one common goal -- the standardization of laboratory accreditations throughout industry.

NACLA is unique in that it is the only recognition organization in which government regulators (Federal Highway Administration, the U.S. Navy, etc.) and industry specifiers (automakers, the airline industry, etc.) play an active role in the formulation of evaluation criteria including recognition, review and approval of accreditation bodies.

The laboratory group of stakeholders in NACLA is represented by the American Council of Independent Laboratories (ACIL). ACIL and NACLA have a Memorandum of Understanding (MOU) to ensure that technical rigor is maintained in the sector-specific technical requirements that will be demanded by a US regulator. NACLA, in turn, develops evaluation criteria for these requirements and includes these criteria in its evaluation of accreditation bodies for recognition. NACLA-recognized accreditation bodies then perform site assessments, which include these sector specific requirements. Through this process, NACLA provides confidence to government and industry that their particular testing and calibration requirements are being uniformly applied and achieved, while avoiding the cost of multiple laboratory audits.

and testing required. The tragic events in Japan spotlight questions surrounding the need for testing for radioactivity. Issues within the past few years dealing with tainted human and pet food underscore the need for the FDA to establish and maintain systems that will address Title II and Title III of the Act both short and long term.

There is a high degree of complexity in ensuring that requirements are being addressed by testing and calibration laboratories. An audit of each testing and calibration provider by each agency and industry specifier would be costly and inefficient; therefore, these organizations rely on third party accreditation providers (accreditation bodies) to conduct laboratory assessments and award accreditations as appropriate. Reciprocity of recognition by government regulators and industry specifiers is a demonstration of confidence that their needs are being met in the laboratory community through NACLA.

NACLA's mission is to ensure reliable testing and calibration results through recognized accreditation. Its composition of regulators, specifiers and stakeholders ensures this mission is realized in an impartial and efficient manner.

NACLA stands willing and ready to assist FDA with the recognition piece to FSMA. A special task force can be brought together to demonstrate the workability of laboratory recognition drawing from other US regulators, accreditation bodies, laboratories and other segments of the industry.

Should anyone at FDA have further questions about this testimony or other related issues, please

Appendix I – NACLA Evaluation Procedures

1) **Application Process**
   a) Written application to the NACLA Evaluation Coordinator.
   b) Application is confirmed.
   c) NACLA evaluation team leader is selected.
   d) Accreditation body (AB) is notified of selection.
   e) AB submits documentation required to begin process.
2) **Pre-Evaluation Process**
   a) Coordinator / Team leader decide on pre-evaluation.
   b) Dates for evaluation team visit negotiated with AB.
   c) Team conducts pre-evaluation of AB prior to visit.
   d) The pre-evaluation report based on documentation submitted to AB and evaluation coordinator.
   e) AB submits corrective action report.
   f) With approval of the action report, the process proceeds to the full evaluation.
3) **Evaluation Process**
   a) NACLA team leader chooses team members and observers.
   b) Team members are contacted.
   c) If pre-evaluations are complete and documentation is adequate, the process continues.
   d) Team leader negotiates full evaluation schedule, scope and timetable.
   e) Opening Meeting at AB.
   f) Evaluation process at AB.
   g) Process concludes at AB with exit meeting and closing report.

b) If team leader accepts corrective action report, the process continues.
    i) If team leader does not accept correction action report, the process is delayed until an acceptable report is received.
c) Team Leader submits recommendation to Accreditation Body and NACLA Evaluation Coordinator.
d) NACLA Evaluation Coordinator and Recognition Council convene meeting to consider final report and consider final report recommendations.