A107-GUIDELINES FOR NEW (APPLICANT) LABORATORIES

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CALA

Trust, measured accurately

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1.0 LENGTH OF VISIT:

The average length of a visit is 2-3 days, depending on the size of the laboratory. CALA assesses every test for which you wish to attain accreditation, so an applicant with a large proposed scope could expect to have an assessment for up to and including 5 days!

2.0 DOCUMENTATION:

One copy of the Quality Manual (or equivalent management system documentation) must be provided at least eight weeks in advance. Electronic copies are uploaded onto a laboratory-specific file-sharing site. The laboratory must complete and submit A18- Cross Reference to Laboratory Management System Form. Other information that must be provided in advance includes any supporting procedures and method validation. It is incumbent on the applicant to have performed an in-depth self-assessment, and be ready for an assessment.

3.0 ASSESSORS:

The number of assessors assigned to the visit is dependent on many factors, including but not limited to the number of appendices to be assessed and the expertise required.

4.0 LANGUAGE:

As much as possible, assessors assigned can speak the local language. If a translator is required, the laboratory must provide one at the laboratory's cost.

CALA has translated some documents into French and Spanish, to facilitate the assessment process. However, the working language is English and the report given at the end of the assessment is in English. Responses to required actions may be in the local language (e.g., Spanish or French) but laboratories are asked, at a minimum, to translate the summary table of corrective actions into English. While the assessors or staff can generally review the responses in the language of choice, the file eventually has to be reviewed by the CALA Advisory Panel and Accreditation Council, and there are more limitations in language capability.

5.0 OVERVIEW OF THE PROCESS:

An opening meeting is held first to brief laboratory management and staff on the assessment process. Key personnel that need to attend the meeting include laboratory management staff, the person(s) responsible for the implementation and maintenance of the management system, and senior staff directly or indirectly responsible for the laboratory. It is appropriate to have section supervisors there, or depending on the size of the laboratory, you may want to have all the staff in attendance so that they know what to expect. The meeting should be confined to laboratory staff, and not include members of the public or people outside the laboratory that have no bearing on the assessment process or outcome.

The opening meeting is generally followed by an overall tour of the laboratory. The intent of the tour is to provide the assessor(s) with an overview of the facility and test methods.

Most of the first day is spent assessing the management requirements of ISO/IEC 17025. Representatives from management and the person(s) responsible for the management system can expect to spend most of their time with the assessor(s) on this day. During the latter part of the day, one or two test methods may be assessed.

It is appropriate for the assessor(s) to accept modest hospitality, such as a light lunch. Experience shows that since there is a lot of work to do, assessors can only take a very short time for a lunch break and are never available for dinner, as they are busy summarizing the day's findings or doing preparation for the next day.

On the following day(s) of the assessment, the assessor(s) will spend most of their time assessing each test method in the laboratory.

To the best of their ability, the assessors will have wash-up meetings each day with laboratory staff, and keep them updated on the progress of the assessment and any findings. Any concerns by laboratory staff can be raised at that time. An open dialogue between the assessors and laboratory staff is encouraged throughout the assessment.

6.0 ASSESSMENT REPORT:

Following assessment of all the methods, the assessor(s) will provide the laboratory with the assessment report. It is important to note that CALA does NOT have a pass/fail approach; labs will not fail the assessment because nonconformities have been identified on the report. In fact, it's not uncommon to receive a list of items that must be completed within a specified timeframe. This list of nonconformities is basically a list of things to do for the laboratory to conform to the international standard, ISO/IEC 17025. Laboratories should not expect that items will be deleted if corrective actions are put in place before the end of the assessment; an assessment is a snapshot in time, and even if laboratory personnel rush to correct the nonconformity, the nonconformity must still be noted on the report.

Nonconformities on the report fall into two categories:

- Type A nonconformities which need to be corrected within 90 days from the date of the closing meeting before accreditation can be granted, or 45 days from the date of the closing meeting if this is a reassessment for an already-accredited laboratory; and,
- Type B nonconformities, for which responses on the action taken or an action plan must be provided within the specified time frame (90 days for the applicant, 45 days for the accredited laboratories), but supporting evidence of this action will not be required. Action taken in response to a Type B nonconformity will be reviewed at the next assessment.

9.0 CLOSING MEETING:

The closing meeting should take no longer than one hour, depending on the size of the visit. The closing meeting is not the appropriate time to provide further information or argue findings – this can be avoided by constant communication throughout the visit.

10.0 POST-ASSESSMENT:

The assessor(s) will send all the checklists and materials related to the visit to the CALA office. Staff will review the assessment report, and may change the grading of a nonconformity from an A to a B or vice versa. There are mechanisms in the process to dispute or appeal decisions (see Q28-*Disputes and Appeals within CALA Programs*). An official copy of the report and a form to summarize corrective actions will be sent via e-mail to the laboratory within two-three weeks.

The laboratory must respond to all nonconformities graded as "A" within the timelines noted above, and send objective evidence for each item. The laboratory must also complete and submit an English copy of the electronic (Word) table, as this document will form the basis of the approval process. If the laboratory has problems completing the form in English, the form can be completed in both English and the local language.