GUIDELINES FOR NEW (APPLICANT) LABORATORIES

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 during this initial visit. So, an applicant with a large proposed scope could expect to have an assessment for up to and including 5 days!

Documentation: One copy of the Quality Manual must be provided at least eight weeks in advance. Hard copies are preferable, but if electronic copies are sent to CALA, they must be able to be printed to facilitate the review of the documentation prior to the assessment. The laboratory must also complete and submit a Quality Manual Cross Reference Form (A18) and the CALA Rating Guide (A02). The latter is important to ensure that a new laboratory has done a self-assessment, and is ready for an assessment. Other information that must be provided in advance includes any supporting procedures and method validation. This information may be submitted via FTP or on a CD-ROM.

Assessors: There are generally two assessors on a first visit. Sometimes because of the laboratory size or language requirements, there may only be one assessor assigned. CALA assessors generally still work in a laboratory themselves, and have had intensive training in assessment processes and ISO/IEC 17025:2005. There are some CALA-trained assessors based in Lima, Peru that have all the same qualifications as volunteer assessors from Canada, that may be assigned to international laboratories because of language requirements.

Language: As much as possible, assessors assigned can speak the local language. If, however, a translator is required, this must be at the expense of the laboratory.

CALA has translated some documents into French and Spanish, to facilitate the assessment process. However, the working language is English so 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.

Overview of the Process: An opening meeting is held first to brief laboratory management and staff on the assessment process. Key personnel that should be at the meeting include the Technical Manager and Quality Manager (however named), and senior staff directly or indirectly responsible for the lab. It is appropriate to have section supervisors there, or

depending on the size of the laboratory, you may want to have all your staff there 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.

This is generally followed by an overall tour of the laboratory, just to give the assessors an overview of the facility and test methods.

Most of the first day is spent assessing the management requirements of ISO/IEC 17025. Both assessors are generally involved in this, and the Technical Manager and Quality Manager can expect to spend a lot of time with the assessors on this day. Near the end of the day, one or two methods may be assessed.

It is appropriate for the assessors 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 preparing for the next day.

On Day Two of the assessment, the assessors will spend time looking at each method in the laboratory; generally, one assessor will spend time with one analyst, while the other assessor will spend time with a different analyst, to facilitate assessment of the proposed scope.

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 should be raised at that time. An open dialogue between the assessors and laboratory staff is encouraged throughout the assessment.

Assessment Report: Following assessment of all the methods, the assessors will provide the laboratory with the site visit report. It is important to note that CALA does NOT have a pass/fail approach; labs will not fail the assessment because non-conformances 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 non-conformances 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 lab personnel rush to correct the non-conformance, the non-conformance must still be noted on the report.

Findings on the report fall into two categories:

- Required *A* items, 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,

- Required *B* items, 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 Required *B* item will be reviewed at the next assessment.

Closing Meeting: 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. The closing meeting should take no longer than one hour, depending on the size of the visit.

Post-Assessment: The assessors will send all the checklists and materials related to the visit to the CALA office. Staff will review the assessment report, and may change a finding 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 an electronic Action Response Form will be sent to the laboratory within two-three weeks.

The laboratory must respond to all *A* findings 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.