

CALA ACCREDITATION PROGRAM INSTRUCTIONS

RESPONSES TO NONCONFORMITIES

In order to maintain good turnaround time on CALA's review of your responses to nonconformities, the following instructions must be followed. Failure to do so may result in CALA refusing to review the responses. In this case, the responses will be returned to the laboratory, with a request to reorganize and resubmit the documentation in accordance with these instructions.

1. By the implementation date on the assessment report, please complete and submit the laboratory responses to any required action in CAMS. The laboratory will receive an email notification once the final assessment report is available in CAMS. Please note that the due date is calculated from the date of the closing meeting.
2. For Nonconformities graded as "A": The laboratory response shall include a brief description of the action taken to address the nonconformity in the space provided. The laboratory shall also provide an analysis of the extent and cause of the nonconformities (ISO/IEC 17025 8.7.1b). Objective evidence must be submitted for every item that is a nonconformity graded as "A". Examples include: copies of standard operating procedures (SOPs), photographs, calibration certificates, paid invoices, packaging slips, training records, copies of analytical runs, etc. Written affirmation, without supporting documentation, cannot be accepted as a satisfactory response to a requirement. This includes requirements relating to management reviews and internal audits. Please upload the relevant supporting documents in CAMS. CALA will only accept documents submitted electronically via CAMS
3. For Nonconformities graded as "B": The laboratory shall include a brief description of the action taken or planned to address the nonconformity. Supporting documentation may be included as appropriate. This will be followed up at the next assessment.
4. Please identify each piece of documentation and objective evidence so that it is clear as to which nonconformity it applies.
5. Be cognizant of correction versus corrective actions! For example, if a labeling nonconformity was observed during the assessment, a laboratory may submit a photograph as evidence that the nonconformity was corrected, however, CALA staff may request evidence that staff have been trained/re-trained on the laboratory's policy/procedure on labeling. Laboratories are advised that part of investigating a nonconformity is determining the extent of the impact of the nonconformity with the entire laboratory operation.

6. For revisions to the laboratory's policies or procedures, clearly highlighting the changes will facilitate the review process.
7. If you have any questions, please contact your assigned Accreditation Officer.

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8.0 REVISION HISTORY

Revision Number	Revision Date	Nature of Revision
1.40	August 31, 2022	Removed references to A114 -Action response form and use of FTP. Added CAMS.