

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 an electronic copy of A114 - Action Response Form in Microsoft Word format, which is emailed to the laboratory contact.
2. For Nonconformities graded as "A": In the column labeled Corrective Action, please include a brief description of the action taken to address the nonconformity. The laboratory shall also provide an analysis of the extent and cause (e.g. root cause analysis) of the nonconformities. In the column Supporting Documentation, please reference the supporting objective evidence (e.g., page # and section X of standard operating procedure Y). Please do not modify the table or add any formatting (i.e., bullets, numbered lists, indenting, etc.).
3. For Nonconformities graded as "B": In the column labeled Corrective Action, please include a brief description of the action taken or planned to address the nonconformity. Supporting documentation is not required.
4. 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.
5. Please identify each piece of documentation and objective evidence so that it is clear as to which nonconformity it applies. If submitting hard copies, please avoid use of paper clips and post-it notes, as these may fall off and become lost.
6. 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 would request evidence that staff are aware of the laboratory's policy/procedure on labeling.
7. For revisions to the laboratory's policies or procedures, highlighting the changes will facilitate the review process.
8. Laboratories are advised that part of investigating a nonconformity is determining the extent of the impact of the nonconformity with the entire laboratory operation.

9. Submission instructions:

- a) An electronic copy of the completed A114 – Action Response Form in Microsoft Word format is required. This completed form may be submitted:
- via e-mail to Karen Smith (ksmith@cala.ca); or,
 - uploaded to a secure site using File Transfer Protocol (FTP) using the login credentials and instructions provided to your laboratory via email. If this option is chosen, it is imperative that you notify CALA that the table and responses have been uploaded. Please notify Karen Smith (ksmith@cala.ca).
- b) Objective evidence shall preferably be submitted in an electronic format. If this is not possible, please contact the Accreditation Officer assigned to your file for directions.

To submit objective evidence electronically, laboratories are encouraged to use FTP. Alternatively, electronic copies of supporting documentation may be submitted on a USB memory stick or equivalent, in a Word or Adobe format. Do not send objective evidence by email unless there is prior agreement by CALA accreditation staff.

10. If you have any questions, please contact one of the following Accreditation Officers:

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Andrew Lewis	(alewis@cala.ca)
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