

# CALA ACCREDITATION PROGRAM INSTRUCTIONS

## RESPONSES TO NON-CONFORMITIES

In order to maintain good turnaround time on CALA’s review of your responses to non-conformities, 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*, which is emailed to the laboratory contact.
2. **For Non-conformities graded as “A”:** In the column labeled *Corrective Action*, please include a brief description of the action taken to address the nonconformance. 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 Non-conformities graded as “B”:** In the column labeled *Corrective Action*, please include a brief description of the action taken or planned to address the nonconformance. Supporting documentation is not required.
4. Objective evidence must be submitted for every item that is a non-conformity 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 non-conformity 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 nonconformance was observed during the assessment, a laboratory may submit a photograph as evidence that the non-conformity was corrected, however, CALA staff would likely request evidence that staff are aware of the laboratory’s policy/procedure on labeling.

7. For revisions to the laboratory's Quality Manual, please send only a copy of the modified sections, not the complete Manual. Highlighting the changes will also facilitate the review process. If the Quality Manual revisions are extensive, an entire new Manual may be requested by CALA.
8. Laboratories are advised that part of investigating a non-conformity is determining the extent of the impact of the non-conformity with the entire laboratory operation.
9. Submission instructions:

a) An electronic copy of the completed A114 – *Action Response Form* is required. This completed form may be submitted:

- via e-mail to Karen Smith ([ksmith@cala.ca](mailto: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](mailto:ksmith@cala.ca)).

b) Objective evidence can be in an electronic format, or hard copies may be submitted.

To submit objective evidence electronically, laboratories are encouraged to use FTP. Alternatively, electronic copies of supporting documentation may be submitted on a CD, in a Word or Adobe format. Do not send objective evidence by email.

If submitting hard copies of objective evidence, please forward the documents and records to:

CALA  
Suite 102  
2934 Baseline Rd.  
Ottawa, Ontario  
K2H 1B2

Attention: Karen Smith

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

Margaret Smetny-Sowa	( <a href="mailto:margaret@cala.ca">margaret@cala.ca</a> )
Andrew Lewis	( <a href="mailto:alewis@cala.ca">alewis@cala.ca</a> )
Janet Dickson	( <a href="mailto:jdickson@cala.ca">jdickson@cala.ca</a> )
Phone: (613) 233-5300	Fax: (613) 233-5501