

INSTRUCTIONS
RESPONDING TO THE ASSESSOR DEFICIENCY REPORT

Deficiencies cited during your A2LA assessment must be addressed and resolved through your formal Corrective Action Process (per Section 4.10 of ISO 15189:2007). To promote ease and efficiency in our review of your corrective action, we recommend the following structure for your response:

- (1) It is extremely helpful to both A2LA staff and the Accreditation Council if each deficiency is restated on a separate page with the corresponding corrective action explanation and objective evidence attached. An example of how this may be accomplished is attached to this instruction sheet.
- (2) Alternatively, deficiency responses can be addressed in a cover letter with a clear indication as to where any corresponding supporting documentation/attachments can be found (e.g., "See Attachment 2" or "See Section 5.A of Quality Manual") in your cover letter's enclosures.

Electronic submission of your formal corrective action response is acceptable. However, printing multiple documents and attachments can be time consuming and difficult to reassemble. Therefore, A2LA will only accept the electronic submission of corrective action responses if they are submitted in the following format:

- Submission of each individual corrective action response as one attachment per deficiency (including root cause analysis and all applicable supporting objective evidence) in the aforementioned structure.

Any electronic submission that is not decipherable will be refused and your laboratory will be asked to provide your corrective action measures in hard copy format.

1. Objective Evidence

Per ISO 15189:2007, clause 4.10.1, your corrective action must start with an investigation to determine the root cause of the deficiency. ***The corrective action response must include the documented results of the root cause analysis and the objective evidence (e.g. lab procedures, paid invoices, packaging slips, training records) to indicate that the corrective actions have been implemented/completed to address the root cause.*** If addressing a deficiency to your Quality Manual, however, please do not send us your entire revised Manual. Send only a copy of the revised section(s) that specifically addresses the deficiency. Further details regarding the content of your response follow. (*Note: It is possible that the laboratory disagrees with a deficiency. The laboratory should then explain in its response why it disagrees with the assessor.*)

If requesting an exception to the A2LA Traceability Policy in response to a deficiency, you are required to submit the following information for each, individual case for which an exception is requested:

1. Equipment name and model;
2. Parameter and range of calibration needed;
3. Key words used in any website search for an accredited calibration provider;
4. List of all sources investigated (e.g., specific accreditation body websites, hardcopy directories, state metrology labs, etc.)
5. Objective evidence that the measurement being provided by your present calibration vendor is traceable to the SI (a reverse traceability study verifying the sources of calibration to include a certificate of calibration showing direct calibration by an NMI or by an A2LA recognized accredited laboratory). A traceability statement found on the calibration certificate is not adequate objective evidence.

If an exception is granted, you will be notified in writing, however circumstances surrounding the exception will be re-evaluated during your next full assessment and a deficiency will again be cited if you are still using a calibration provider that does not meet the A2LA Traceability Policy.

Please note also that if you are using a calibration provider that does not meet the A2LA Traceability Policy, to satisfy the deficiency you do not need to immediately re-calibrate the equipment in question using an acceptably accredited calibration source. You must demonstrate in your corrective action response that you will use an acceptable source of calibration for the next regularly scheduled calibration cycle. An acceptable source is a calibration laboratory accredited by A2LA or one of our mutual recognition partners. We invite your attention to our website www.a2la.org for a listing of our partners.

2. Confidentiality

Once A2LA staff has reviewed your response and determined the supporting documentation to be complete, your assessment package is copied and sent to each Accreditation Council (AC) member voting on the assessment package. We make every effort to maintain the confidentiality of your laboratory's assessment information. We also wish to avoid the possibility of conflict of interest with the AC members who cast the votes to accredit your laboratory. A2LA will provide you with a list of our Accreditation Council members prior to sending your assessment package to the Council so that you can assist us in avoiding a possible conflict of interest by indicating which Council members should not receive your assessment package.

3. Lab Code and Assessment ID

Please include your MASTER CODE and ASSESSMENT ID in the top right-hand corner of each page of your corrective action response and supporting documentation.

4. Timing and Distribution of Corrective Action Response

Please respond to the Assessor Deficiency Report with a detailed corrective action response within **one month** after the date of the exit briefing. One copy of the corrective action response should be forwarded to A2LA and one copy should be forwarded to the assessor(s).

Observations may be written when the assessor questions the practice or competence of your lab but there is not enough supporting objective evidence to justify a deficiency or the issue cannot be tied to the accreditation requirements. Your laboratory *does not* have to respond to observations in order for accreditation to be granted. However, the observations are part of the assessment record and will be followed up by the next assessor to visit your laboratory who will check to see if the observation(s) was addressed by your laboratory, resulting in an improvement, or possibly may have progressed into a deficiency.

Additional information can be found on page 7 of 17 of the "A2LA General Requirements for Accreditation of Medical Testing" (May 2007). Please call A2LA Headquarters if you have any questions.

~ EXAMPLE ~

CORRECTIVE ACTION RESPONSE COVER PAGE

Date:	March 28, 2005
Master Code:	999999
Assessment ID:	0001
Deficiency No.:	1

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| <p>Deficiency Statement:</p> <p>(A2LA Traceability Policy, Section T1) The laboratory is not utilizing an appropriately accredited calibration laboratory for the calibration of its reference thermometer.</p>                                                                                                                                                                                                                                                                                                                                   |
| <p>Root Cause:</p> <p>Due to the lengthy calibration cycle for this thermometer (5 years), we had not yet identified an accredited calibration laboratory since it had not yet appeared in our calibration recall schedule.</p>                                                                                                                                                                                                                                                                                                                   |
| <p>Corrective Action:</p> <p>An A2LA-accredited laboratory has been identified to perform the required calibration when it is next due (December 2006) and a quote for their services has been obtained. The laboratory approved vendor list has been updated and the equipment list has been reviewed to ensure that appropriate calibration laboratories have been identified for all required calibrations.</p>                                                                                                                                |
| <p>Specific Supporting Documentation Attached:</p> <p>(Attachment 1-A) Quote for services from accredited calibration laboratory.</p> <p>(Attachment 1-B) Approved vendor list, indicating addition of the thermometer calibration laboratory and removal of prior vendor for this service.</p> <p>(Attachment 1-C) Calibration Recall Schedule indicating use of accredited calibration laboratory when thermometer is due again. Schedule also indicates our review of all equipment listed to ensure use of an accredited calibration lab.</p> |