	<i>The American Association for Laboratory Accreditation</i>	
	I602 – INSTRUCTIONS FOR RESPONDING TO THE MEDICAL DEFICIENCY REPORT	Document Issued: January 18, 2010 Page 1 of 3

Deficiencies cited during your A2LA medical assessment must be addressed and resolved through your formal Corrective Action Process (per Section 4.10 of ISO 15189:2007). Please provide A2LA with your corrective action form (e.g. Corrective Action Request (CAR) form) and all supporting and applicable objective evidence of closure for *each* condition level and non condition level deficiency cited.

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. revised/updated lab procedures, paid invoices, packaging slips, training records, etc.) to indicate that the corrective actions have been implemented/completed to address the root cause.***

Root cause analysis is the most challenging aspect of the corrective action process and should be used as a tool for continuous improvement, which may reduce or eliminate the likelihood of future deficiencies.

Understanding why an event occurred is the key to developing effective corrective actions. In some cases, the root cause is singular and easily discerned; in most cases it is not, and there may be multiple root causes. Because of this, there is no single ‘recipe’ that can be followed. While it is impossible to create a procedure that would apply to all scenarios, there are some guiding principles which can be employed, the most important of which is that the root cause should address the question: “Why did this deficiency occur?” Other points to consider:

- Statements of root cause which are essentially a ***restatement of the deficiency*** provide no new information beyond the deficiency and are of little benefit to you and are not considered to be an acceptable response by A2LA. In these instances, the root cause is a result of the laboratory asking “why was this deficiency cited?” instead of “why did this deficiency occur?”
- Each deficiency shall be evaluated independently.
- While each deficiency and its associated root cause must be approached individually, trends in the identified root causes for a group of deficiencies is a strong indicator that further investigation is needed. For example, upon conclusion of an assessment during which 8 deficiencies were cited, it is determined that the root cause of 6 of the 8 deficiencies pertains to employee training. In this example, additional investigation into the employee training program would be prudent and should be evident in the response supplied to A2LA.

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- The investigation which begins by asking “why did this deficiency occur?” will uncover a reason why the deficiency occurred. A proper root cause investigation will continue to ask ‘why did this occur’ until you can no longer identify a reason. At this point you can be reasonably assured that you have isolated the crux of the issue.

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 medical laboratory disagrees with a deficiency. The medical 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 using the attached A2LA *F106 – Request for Exception to the Policy on Measurement Traceability* 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 medical 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

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possible conflict of interest by indicating which Council members should not receive your assessment package.

3. MASTER 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

FOR NEW MEDICAL LABS – if you fail to respond in writing within four months after the date of the exit briefing, you may be required to submit a new application and be subject to new fees and reassessment should you wish to pursue accreditation after that time. If you fail to resolve all deficiencies within six months of being assessed, you shall be subject to be reassessed at your expense.

FOR RENEWAL MEDICAL LABS – you must respond in writing within 30 days of the exit briefing, and resolve all deficiencies within 60 days of the exit briefing. *Failure to meet these deadlines may result in adverse accreditation action (e.g. reassessment or suspension of accreditation). Further, extensions of accreditation are not granted when delays are due to the laboratory’s failure to respond to requests within established deadlines.*

In order to aid us in providing an efficient and timely review of your corrective action, we discourage multiple responses for single deficiencies or packages containing only partial responses that address only a portion of the deficiencies cited. Please limit the number of submittals by providing the responses as a complete, single package. The AcO will not queue your corrective actions for review until a response for all open deficiencies has been received.

When supplying corrective action responses in hard-copy (printed) form, one copy of the response shall be forwarded to A2LA and a courtesy copy should be forwarded to the medical assessor(s). When supplying responses electronically (via email), please be sure to copy the medical assessor(s) on the message.

Observations may be written when the assessor questions the practice or competence of your medical lab but there is not enough supporting objective evidence to justify a deficiency or the issue cannot be tied to the accreditation requirements. Your medical 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 medical laboratory who will check to see if the observation(s) was addressed by your medical laboratory, resulting in an improvement, or possibly may have progressed into a deficiency.

Please call A2LA Headquarters (301 644 3248) if you have any questions.



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F106 – REQUEST FOR EXCEPTION TO THE POLICY ON MEASUREMENT TRACEABILITY

Document Revised:
August 22, 2008

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LABORATORY NAME:

MASTER ID:

ASSMNT ID:

CERT NO(s):

I hereby request an exception to *P102 - A2LA Policy on Measurement Traceability* for the listed equipment and the associated non-accredited calibration provider (*please use a separate form for each exception requested*). Please complete the information requested below and attach objective evidence that the measurement being provided by your present calibration provider is traceable to the SI (*a reverse traceability study verifying the sources of calibration to include a certification of calibration showing direct calibration by an NMI or by an accredited laboratory*).

REQUIREMENT	LAB INPUT	RESERVED FOR A2LA STAFF
1. Equipment name, model, and identification number:		<input type="checkbox"/> Exception Granted
2. Parameter and range of calibration needed:		<i>This exception is valid for the period of time covered by this assessment ID only.</i>
3. Key words used in any website search for an accredited calibration provider;		<input type="checkbox"/> Exception Denied
4. List all sources investigated (e.g. specific accreditation body websites, hardcopy directories, state metrology labs, etc.)		Reason:

Authorized Representative: _____

Signature: _____ Date: _____