NOTE: The flexible scope option is only available to laboratories accredited in the biological, chemical and forensics fields of testing. It is further limited to only those activities related to chemical, biochemical and molecular biology testing. This option will be reviewed on a case-by-case basis, and the final decision on allowing the flexible scope option rests with A2LA.

There are circumstances in which a laboratory performs testing activities for which it cannot identify either standard test methods prepared by national, international, or professional standards writing bodies or in-house developed non-standard methods on their fixed scope of accreditation. These situations usually arise when the laboratory requires flexibility in allowing for changes in the matrices within a product area (flexibility concerning object/matrix/sample) or with respect to parameters (flexibility concerning parameters/components/analytes).

If a laboratory wishes accreditation under the flexible scope option, then they must:

- Have previously demonstrated their competence to A2LA by having been first accredited to a defined set of published or in-house developed methods. As such, a transition to the flexible scope option in most cases could not occur until their surveillance or first reassessment visit.

- Demonstrate that a fixed scope is too restrictive for the work they are currently undertaking and that a flexible scope is justified.

- Demonstrate that it has a management system which will control the flexible scope so that all tests are carried out in accordance with the requirements for accreditation.

- Demonstrate that it has the technical competence and depth of experience to support the granting of a flexible scope.

- Control and maintain on record the modifications and updates of its test methods or development activities. The laboratory must retain the underlying results and other relevant data (normally in the form of a validation and/or verification report) per ISO/IEC 17025 section 5.4 and make them available for review upon request at any time.

- Annually (at the time of Renewal or Annual Review) and at the request of A2LA provide A2LA with an update on the methods which they have validated since the last assessment and regularly update their Proficiency Testing Plan accordingly (NOTE: Some accreditation programs require prior demonstration of proficiency
If available) before accreditation can be conferred and similar participation would be required for laboratories with flexible scopes).

- Ensure that any modifications to methodology do not incorporate new measurement principles that were not previously identified in their scope of accreditation. For those modifications to methodology that incorporate new measurement principles not previously evaluated by A2LA, laboratories must notify A2LA via the formal scope expansion process as outline in form F108 – Request for Expansion of Scope of Accreditation - Testing.

If you have any questions concerning this arrangement, please contact us at 301 644 3248.

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APPENDIX A - Document Revision History

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<td>12/1/2011</td>
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