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R104 – GENERAL REQUIREMENTS:

ACCREDITATION OF FIELD TESTING AND FIELD

CALIBRATION LABORATORIES

(August 2009)

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INTRODUCTION

A2LA uses as the basis for all of its accreditations (of both testing and calibration laboratories) ISO/IEC 17025:2005, “General requirements for the competence of testing and calibration laboratories”. These requirements have become the standard throughout the world, and identifying laboratories that have demonstrated compliance with these requirements has become the basis for mutual recognition agreements with accreditation systems in other countries. A2LA has also developed “Specific Requirements” which are an elaboration on or interpretation of ISO/IEC 17025, plus those additional requirements applicable to a certain field, a certain technology or a certain type of test/calibration. Examples of A2LA Specific Requirements include the Environmental Program Requirements, Calibration Program Requirements and Automotive EMC Program Requirements. Laboratories seeking accreditation in any of these programs must also meet the requirements outlined in the Specific Requirements relevant to the program.

Although ISO/IEC 17025 is applicable to field testing or field calibration, it has been recognized internationally that additional, interpretive guidance may be necessary so mutual confidence between international testing and calibration services can be sustained. This mutual confidence leads to the formation of mutual recognition agreements based on the equivalence of the operations of various accreditation bodies which, in turn, leads to the international acceptance of test/calibration data.

1 SCOPE

All laboratories accredited by A2LA must meet the requirements of ISO/IEC 17025:2005. This document describes additional accreditation requirements specifically applicable to laboratories performing tests or calibrations outside of their permanent laboratory, at the customer’s premises or ‘in the field’. Laboratories may be accredited for field testing or calibration regardless of their affiliation with an accredited or applicant “permanent laboratory”, as defined in Section 3 of this document. However, if the field testing laboratory is legally affiliated with a “permanent laboratory”, this permanent laboratory must be A2LA-accredited as well.

2 REFERENCES

ISO/IEC 17000, “Conformity assessment – Vocabulary and general principles”

ISO/IEC 17025:2005, “General requirements for the competence of testing and calibration laboratories”

3 DEFINITIONS

- 3.1 **Permanent Laboratory:** A calibration or testing laboratory erected on a fixed location. This is the laboratory location (address) denoted on the scope of accreditation.
- 3.2 **Organization:** Company, Consultancy, Partnership, other body or individual who does not necessarily have a permanent laboratory but who tests or calibrates the characteristics or performance of materials or products at a

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customer specified field location. For organizations that only perform field testing/calibration, the address denoted on the accredited scope of accreditation will be that of the organization’s office or headquarters where records and equipment are kept. Further, the scope will clearly delineate that only field testing is performed by this organization.

3.3 **Field:** Any location where testing or calibration takes place as defined in 3.4 below.

3.4 **Field Testing/Calibration:** Testing/Calibration performed by staff of a laboratory or organization outside of the premises or grounds on which the permanent laboratory or the organization’s permanent base or headquarters is located. Field testing/calibration may include sampling where it forms part of the documented calibration or test procedure. Accreditation for sampling alone is also offered and *R219 – Specific Requirements: TNI Field Sampling and Measurement Organization Accreditation* should be consulted for further details.

Field Tests or Calibrations are normally performed under two categories:

- Field tests or calibrations performed by staff sent out in the field by an accredited, permanent laboratory. This includes in-situ testing¹.
- Field tests or calibrations performed in the field by organizations that do not have a permanent laboratory.

3.5 **Field Laboratory:** A testing or calibration laboratory facility set up in a dedicated location or at a customer’s premises, outside of the organization’s permanent base or headquarters for the duration of the testing or calibration activities but not for periods expected to exceed three years (e.g. a Construction Materials laboratory set up at an airport construction site, a calibration laboratory under contract set up in support of a customers manufacturing process). All field laboratories must be identified on the application paperwork, be assessed as part of the permanent laboratory assessment, and be identified on the laboratory’s scope of accreditation.

3.6 **Mobile Laboratory:** Fully equipped, self-contained, transportable testing or calibration laboratory capable of performing tests or calibrations under controlled environmental conditions. (Note: Mobile laboratories are subject to the same terms of accreditation as a field laboratory. Mobile laboratories left at one location for three years or more will be subject to the same terms of accreditation as a permanent laboratory.)

4 Management Requirements

4.1 Organization

No additions

4.2 Management system

4.2 S.1 The quality manual or related quality documentation of the permanent laboratory or organization shall contain a section covering the arrangements for the field operations. This shall include:

- 4.2 S.1.1 an up-to-date record of field laboratory locations and the purpose for which they were used, including identification of any mobile laboratories (See NOTE below);

¹ In-situ: Testing or calibration of a device or system performed at the place of its installation.

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NOTE: The records required may be maintained separately and not necessarily part of the quality manual.

4.2 S.1.2 details of how the management system is applied to and incorporates field testing/calibration (e.g., an organizational chart for the permanent laboratory showing lines of responsibility and authority for field testing/calibration, etc.) as well as arrangements for the supervision of field testing or calibrations where the field is not controlled by the customer but rather by a third party.

4.2 S.1.3 identification of approved signatories, criteria for signatory approval and limits of signatory authority. This criteria should include an assessment of the following attributes:

- qualifications and experience;
- position in the overall staff structure;
- familiarity with the calibration or test procedures and awareness of any limitations of these procedures;
- knowledge of the procedures for recording, reporting and checking results;
- awareness of the needs for periodic recalibration of equipment; and
- awareness of the requirements and conditions for A2LA accreditation, particularly those related to calibration or test reports.

4.2 S.2 The relevant parts of the quality manual shall be available to the personnel performing field testing/calibration.

4.3 Document control

No additions

4.4 Review of requests, tenders and contracts

No additions

4.5 Subcontracting of tests and calibrations

No additions

4.6 Purchasing services and supplies

No additions

4.7 Service to the client

No additions

4.8 Complaints

No additions

4.9 Control of nonconforming testing and/or calibration work

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No additions

4.10 Improvement

No additions

4.11 Corrective action

No additions

4.12 Preventive action

No additions

4.13 Control of records

4.13 S.1 Procedures shall exist for recording and reporting all results obtained in the field and shall be coordinated with the system operating in the permanent laboratory (where appropriate). Records of original observations, calculations, data transfers and checks shall be identifiable by person and date. Records shall be made in a permanent manner and maintained so that they are not obliterated by rain, humidity, spills, leaks or other environmental factors that may affect the immediate or future readability of the records.

4.13 S.2 Procedures shall exist for ensuring the security and confidentiality of test/calibration data obtained and held in the field.

4.14 Internal audits

4.14 S.1 Internal audits of the field laboratory's management system shall be conducted using similar procedures as those applied to a permanent laboratory.

4.14 S.2 The designated internal auditor shall visit field and mobile laboratories as part of the internal audit process. The audit process shall contain specific elements to assess whether field tests and/or calibrations continue to comply with the requirements of the management system.

4.15 Management reviews

4.15 S.1 Management review shall take account of field testing and calibration activities.

5 Technical requirements

5.1 General

No additions

5.2 Personnel

5.2 S.1 The permanent laboratory or organization shall have procedures for ensuring that staff performing field tests/calibrations are properly trained and competent. Evidence of the competence of staff performing the

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specific field tests or calibrations shall be available. (This evidence should include training records, appropriate analysis of blind proficiency samples (where available) and other demonstrations of method proficiency.)

5.2 S.2 Field personnel not employed or sub-contracted by the permanent laboratory or organization shall not assist in the performance of accredited tests or calibrations unless adequately supervised by trained staff employed or sub-contracted by the permanent laboratory or organization. Field personnel not employed or sub-contracted by the permanent laboratory or organization shall not perform accredited tests or calibrations, unassisted, under any circumstances.

5.3 Accommodation and environmental conditions

5.3 S.1 Where the environment may affect the instrumentation, the test specimen or the required accuracy and precision of measurement, the data shall be qualified per the requirements of these criteria.

5.3 S.2 Where tests/calibrations are undertaken in a hostile or unstable environment or in an environment that may affect the test or calibration results, there shall be procedures for monitoring these conditions and the effect of the environment on the performance of the test or calibration. This monitoring shall be documented.

5.3 S.3 There shall be provisions for restricting access to the field laboratory when unrestricted access could invalidate the test or calibration results.

5.4 Test and calibration methods and method validation

5.4 S.1 Up-to-date test/calibration procedures (whether standard methods or internal procedures/amplifications/modifications) shall be available to all staff performing field tests or calibrations.

5.4 S.2 Procedures shall exist for the supply and updating of test/calibration procedures required by staff performing field work.

5.4 S.3 Where appropriate, the uncertainty of measurement must be estimated using appropriate methods of analysis, taking into account the prevailing environmental conditions. Where it is not appropriate to determine measurement uncertainty, the laboratory shall demonstrate that method performance is within the defined control limits of the reference test method.

Note 1: The best measurement capability for field calibrations will normally be larger than that stated for the permanent laboratory. In estimating the field uncertainties, the calibration laboratory shall consider what is the best environment that can be expected at a customer site. [See Appendix A].

Note 2: The ISO Guide to the Expression of Uncertainty in Measurement contains internationally accepted methods for determining measurement uncertainty. This document may be obtained through ANSI Customer Service at 212 642 4900.

5.5 Equipment

5.5 S.1 There shall be procedures for operating, maintaining, storing and calibrating equipment used in field testing or calibration. Equipment maintenance and calibration records shall include the location, date and operator for all maintenance and calibration as well as details of storage between use.

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5.5 S.2 Appropriate checks shall be made to confirm the calibration status and fitness for use of equipment before field testing or calibration begins. Where such checks cannot be made (for equipment whose performance is not sensitive to movement), calibration status and fitness for use shall be checked in the permanent laboratory or at the organization’s permanent base before and after field testing or calibration. Equipment whose performance is sensitive to movement shall be verified/calibrated in the field before use. If equipment is found to be unfit for use and/or out of calibration, it shall not be used and shall be immediately withdrawn from service. The laboratory shall examine the effects of such equipment on previous tests or calibrations.

5.5 S.3 If equipment other than that owned by the permanent laboratory or organization is used, the provider of such equipment shall be considered as a supplier of outside services/supplies, subject to the requirements specified in Section 4.6 of ISO/IEC 17025:2005. The laboratory shall document and archive calibration certificates (where appropriate) and other relevant details of the “borrowed” or rented equipment. Borrowed or rented equipment must be inspected for damage or malfunction before each use. It is the field laboratory’s responsibility to ensure that borrowed or rented equipment receives the same checks/calibrations and other controls as laboratory-owned equipment, prior to and during use.

5.5.S.4 A laboratory that performs calibrations on a customer’s site shall make a full list of all the equipment that is transported. For each parameter, the laboratory shall define the BEST UNCERTAINTY that it can achieve with that transported equipment. [See Appendix A for additional information on Calibration Scopes.]

5.6 Measurement traceability

5.6 S.1 When it is necessary to utilize reference standards, adequate measures shall be taken to ensure that the necessary calibration status is maintained during transportation and while in the field. The response of such reference standards to environmental changes or other relevant parameters shall be known and documented.

5.6 S.2 Reference standards shall be maintained in a suitable environment at all times, such that handling, transport and storage do not invalidate their calibration status.

Note 1: A reference standard is a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

5.7 Sampling

No additions

5.8 Handling of test and calibration items

5.8 S.1 Appropriate precautions shall be taken during storage, handling, transportation and preparation to prevent damage to items field tested or calibrated.

5.9 Assuring the quality of test and calibration results

No additions

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5.10 Reporting the results

5.10 S.1 Results obtained from field tests/calibrations shall be identified as such on issued Certificates/ Reports, whether they form part or all of the information presented.

5.10 S.2 In addition to the information specified in ISO/IEC 17025, Section 5.10, Certificates/Reports shall contain any details relevant to the calibration/test such as location of calibration/test item.

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APPENDIX A

Impact on the A2LA Accreditation Process

1. Application

At the time of application, the laboratory must specifically identify those tests or calibrations that are performed outside of the premises or grounds on which the permanent laboratory or the organization’s permanent base or headquarters is located, whether wholly or partly, including a complete description and identification of any mobile laboratory and its equipment. The laboratory must also identify those personnel involved in field activities and identify each of the tests/calibrations that the field representatives perform. Also, the laboratory must inform A2LA if any of the field representatives are responsible for policy formation, process/procedure development, contract review, or planning, reviewing, approving test or calibration methods or making decision about the test or calibration results.

The laboratory must also identify themselves as an “organization” or an affiliate of a “permanent laboratory”, as defined in Section III of this document. If the field testing/calibration laboratory is legally affiliated with a permanent laboratory, the permanent laboratory must be accredited or must apply for accreditation at the same time.

2. Field Assessment

The assessment, whether or not it includes the assessment of an affiliated “permanent laboratory”, shall entail an examination of the operation of the management system in the field, normally where testing or calibration for a customer is being performed. It shall also entail the assessment of the testing/calibration competency of the field staff, with particular emphasis on those tests or calibrations that can only be carried out in the field. The initial assessment of field testing/calibration capabilities may involve visits to more than one field location.

If the applicant operates a field laboratory, the assessment shall include a full assessment of the capabilities covered at that designated field laboratory.

3. Scope of Accreditation - All Fields

An accredited permanent laboratory which is also accredited for field testing/calibration shall be issued one Scope of Accreditation specifying all tests/calibrations within a particular field which they have been accredited to perform, both in the permanent laboratory as well as in the field. However, all field tests/ calibrations shall be so noted on the Scope.

An accredited field testing/calibration organization (not affiliated with a permanent laboratory) shall be issued a Scope of Accreditation specifying all field tests/calibrations for which they have been accredited. The accredited organization shall be identified on the Scope by the address of the organization’s permanent base or headquarters. If the accreditation is to include more than one mobile testing facility (not affiliated with a permanent laboratory), each mobile facility (as defined in Section II of this document) will be considered as a separate field of testing/calibration and will be issued a separate Scope of Accreditation. If the accreditation is to include a designated field laboratory, that field laboratory’s location (address) and its’ capabilities shall be identified on the permanent laboratory’s scope of accreditation.

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4. Scope of Accreditation - Calibration

It is important that the scopes of accredited laboratories that perform calibrations on customers' sites do not contain potentially misleading values for field capabilities.

The scope of an accredited laboratory shall clearly indicate which parameters and/or calibrations are offered (or not offered) for field work. In cases where the best field and the best in-laboratory uncertainties are different, both uncertainties shall be given on the scope. The assessor shall ask to see the field uncertainty budgets and shall check that the components of uncertainty due to the environment are reasonable.²

In addition, a disclaimer such as the following shall be included on all scopes of accreditation that include field calibration: "*DISCLAIMER - The uncertainties achievable on a customer's site can normally be expected to be larger than the Best Measurement Capabilities (BMC) that the accredited laboratory has been assigned as Best Uncertainty on the A2LA Scope. Allowance must be made for aspects such as the environment at the place of calibration and for other possible adverse effects such as those caused by transportation of the calibration equipment. The usual allowance for the uncertainty introduced by the item being calibrated, (e.g. resolution) must also be considered and this, on its own, could result in the calibration uncertainty being larger than the BMC.*"

5. Proficiency Testing

Organizations accredited for field testing or calibration must meet the proficiency testing requirements outlined in Part C, Section VII of A2LA R101: *General Requirements: Accreditation of ISO/IEC 17025 Laboratories*.

6. Umbrella Organizations

In some cases, an accredited laboratory may employ or contract with another organization to act as their field testing/calibration technicians. If the field work is done completely under the auspices of that other company (i.e., done under their own name and presented on a final report on their own letterhead), then the accredited laboratory must treat this as sub-contracting and must meet all ISO/IEC 17025 and P101 – *Reference to A2LA Accredited Status-A2LA Advertising Policy* requirements related to sub-contracting.

If the field work is to be done under the auspices of the accredited laboratory, then these field technicians must be included in the A2LA assessment process and all requirements for field work as outlined in this document must be applied to that other company, as they are considered to be employees or contractors of the accredited lab. For example, the accredited laboratory must include the field technicians from the other company on their organization chart, must maintain training records for them, must provide them with relevant portions of the accredited lab's quality manual, and must ensure that they do not perform any key functions (e.g., reporting, contract review, etc.). All final reports must be issued by the accredited laboratory and, unless the laboratory wishes to pay for the A2LA assessor to visit the field technicians at their remote locations, all key functions must be performed by and through the accredited laboratory itself.

Under no circumstances may it be stated or implied that the accredited laboratory's accreditation extends to cover any other company. *Furthermore, other organizations supplying field technicians to the accredited laboratory may not use the "A2LA Accredited" symbol in any manner and may make no statements implying A2LA accredited*

² It is often easier for the laboratory to specify environment tolerances outside which no work will be done. The assessor should check these tolerances to see that they are reasonable and consistent with equipment specifications.

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status for the work they perform. The accredited laboratory is responsible for ensuring that their “umbrella” organizations make no such claims or statements. Umbrella organizations may include on their website and in promotional materials a statement that they are a field representative for the accredited laboratory and may link to that accredited laboratory’s website, but only the accredited laboratory itself may use the “A2LA Accredited” symbol and make any statements about the A2LA accredited status of the work they perform through their umbrella organizations. (NOTE: The italicized change to this section is effective as of January 1, 2010 for laboratories already accredited or enrolled in the A2LA program. This highlighted change is effectively immediately for applications received as of September 1, 2009.)

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Document Revision History

Date	Description
July 1, 2001	Introduction updated to reference ISO/IEC 17025. Requirements renumbered to match ISO/IEC 17025 Document Revision History section added.
October 30, 2002	Addition of 2 nd sentence for Note 1 under clause 5.4.S.3 New Requirement 5.5.S.4. Addition of Section 4, Appendix A (Scope of Accreditation - Calibration)
September 13, 2005	Updated to reflect ISO 17025:2005.
April 18, 2008	Terminology changed from ‘Site’ to ‘Field’. Additional clarification of ‘Permanent’ and ‘Field’ laboratories and the requirements associated with them. Addition of Section 6, Appendix A (Umbrella organizations).
August 6, 2009	Section 6 revised to include additional restrictions on use of the “A2LA Accredited” symbol by umbrella organizations. Reference added in Section 3.4 to accreditation for sampling alone.