

Quality and Accreditation Institute

Centre for International Accreditation



Change Adapt Improve

SPECIFIC CRITERIA FOR SITE TESTING AND SITE CALIBRATION LABORATORIES

Issue No.: 02

Issue Date: November 2023

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CHANGE HISTORY

Sl. No.	Doc. No.	Current Issue No.	Revised Issue No.	Date of Issue	Reasons
1	QAI CIA 406	01	02	November 2023 (07 November 2023)	<ul style="list-style-type: none"> Doc name changed from CLA (Centre for Laboratory Accreditation) to CIA (Centre for International Accreditation) Added QAI Office Address

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1. INTRODUCTION

Laboratories seeking accreditation for site calibration/ testing must also meet the requirements outlined in the Specific Criteria relevant to that field /discipline.

This specific criteria document is intended for the laboratories/ entities who are engaged in site testing or calibration.

2. SCOPE

This specific criteria document describes additional accreditation requirements specifically applicable to the laboratories performing tests or calibrations at customer's premises (site) or at a location temporarily set up for a defined duration away from the permanent laboratory or in a mobile facility. Laboratories/ entities may be accredited for site testing or calibration regardless of their affiliation with an accredited “permanent laboratory”, as defined in Section 3 of this document. However, if any laboratory is accredited only for site testing / calibration; the accreditation status of the site testing/ calibration laboratory shall not be used to claim accreditation at the permanent laboratory i.e. the permanent laboratory (if any) shall not be considered as one of the sites. Further in such cases the permanent laboratory/entity shall apply for accreditation of its permanent laboratory separately.

3. DEFINITIONS

1.1 Permanent Laboratory: A testing or calibration laboratory set up in a dedicated location for an indeterminate amount of time.

Note: This is the laboratory location and address denoted on the certificate of accreditation

1.2 Entity: Company, Consultancy, Partnership or other body who does not necessarily have a permanent laboratory but who performs tests or calibrations at site.

Note: This definition may be read only in connection with the purpose of this document

1.3 Site Testing/ Calibration Facility: Testing/ Calibration performed by staff of a

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laboratory or entity at the customer premises or location outside of a permanent laboratory.

Note:

1. Temporary facility created for a defined period is considered as site calibration/ testing facility
2. Site Tests or Calibrations are normally performed:
 - by an accredited, permanent laboratory
 - by an entity that does not have a permanent laboratory

1.4 Mobile Facility: Fully equipped, self-contained, transportable testing or calibration facility capable of performing tests/ calibrations under controlled environmental conditions.

4. MANAGEMENT REQUIREMENTS

The permanent laboratory or entity performing site calibration/ testing shall:

- a. Document and establish procedure and the arrangements for the site/mobile operations.
- b. Maintain a separate list of tests or calibrations that the laboratory/ entity is capable of performing at site under its temporary site facility or mobile facility or at the customer's site.
- c. Provide the details of how the Management system is applied to and incorporates site/mobile testing/ calibration (e.g., an organizational chart for the permanent laboratory showing lines of responsibility and authority for site testing/ calibration etc.) as well as arrangements for the supervision of site/mobile testing or calibrations.
- d. Develop test/ calibration procedures to be followed for site testing / calibration.
- e. Have procedure and appropriate mechanism for verification of equipment before and after site calibration / testing.
- f. For mobile facility; laboratory/ entity shall ensure that the above procedures shall also include precautions to be taken/ considered while performing testing /calibration.

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Note: These precautions including however not limited to control of environmental conditions, vibration control, suitable selection of vehicle etc.

- g. Ensure the availability of relevant documents to the relevant personnel.
- h. Have ensure that audit and review of the site laboratory's quality control system must be conducted using similar procedures as those applied to a permanent laboratory.
- i. Have internal audit plan / schedule covering the site activities also. The designated internal auditor shall visit site and or mobile laboratories as part of the audit and review process. The audit process shall contain elements to assess whether on-site tests and/ or calibrations continue to comply with the requirements of the management system.
- j. Have Management review process ensuring the suitability and effectiveness of site/mobile tests and/ or calibrations activities.
- k. Have procedure ensuring the security and confidentiality of test/ calibration data obtained and held at site.

5. TECHNICAL REQUIREMENTS

5.1 PERSONNEL

- 5.1.1 The permanent laboratory or entity shall have procedures for ensuring that staff performing site tests/ calibrations are properly trained and competent. Evidence of the competence of staff performing the specific site tests or calibrations shall be available.
- 5.1.2 Site testing/calibration shall be performed by the laboratory personnel only, However, assistance/support for operation and functioning of the device under test/calibration can be obtained from the customer.

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5.2 ACCOMMODATION AND ENVIRONMENT

- 5.2.1 Where the environmental conditions may affect the instrumentation and the test/ calibration result the same shall be identified and recorded.
- 5.2.2 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 recorded. The same shall be considered while estimating uncertainty of measurement. Further the actual test/ calibration conditions shall be mentioned in the test/ calibration reports.
- 5.2.3 There shall be provisions for restricting access to the site laboratory where unrestricted access could invalidate the test or calibration results.
- 5.2.4 When a facility is created temporarily for a defined period, all requirements of the permanent laboratory as specified in relevant specific criteria shall be applied for accommodation and environmental conditions.
- 5.2.5 For mobile facility, laboratory shall ensure specific arrangements to minimize vibration, shock, noise etc. due to the operation of the vehicle and ambient conditions and also demonstrate proper environmental conditions same as that required by the relevant specific criteria. Further the mobile facility shall ensure abide by the legal and other road regulations.
- 5.2.6 In both above cases lab shall demonstrate adequate space and housekeeping and shall be free from any external disturbances that may adversely affect the test/ calibration results.

5.3 EQUIPMENT AND REFERENCE MATERIAL

- 5.3.1 The laboratory shall be furnished with all equipment needed for site testing / calibration with valid traceability. The laboratory shall not use any major equipment other than its own for these activities.
- 5.3.2 Laboratory may use same equipments for permanent and site facilities, however,

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in order to ensure that there is no abrupt change in calibration status of the equipment being taken to site, the laboratory shall verify the equipment before taking the it out of the permanent laboratory/ entity and again bringing it back to the laboratory/entity.

The following methods can be practiced for the verification

- 5.3.2.1 In case laboratory/entity is having a separate set(s) of equipments for the site testing/ calibration, these equipments can be verified against the reference standards maintained in the permanent laboratory/ entity.
- 5.3.2.2 Verification using an artifact which is dedicatedly kept with the permanent laboratory or entity before and after site calibrations/ testing. The artifact shall be of reasonably good accuracy and stability. The verification results before and after site calibration / testing shall be within the estimated uncertainty obtained using the artifact.
- 5.3.2.3 The Self check/ calibration facility integrated in equipments.
- 5.3.3 Records of the verifications shall be maintained. 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 and initiate procedure for control of non-conforming work.
- 5.3.4 Laboratory / entity shall prepare and implement a calibration schedule for its equipment used for site testing /calibration. More frequent calibration and intermediate checks of equipment used for site testing /calibration are expected considering the fact that these equipments are subjected to movement and hostile or unstable environmental conditions.
- 5.3.5 There shall be procedures for safe handling, transport, storage, use, and planned maintenance of equipment/ reference standard used in site testing or calibration.
- 5.3.6 Laboratory shall identify and authorize personnel to perform site testing / calibration and operate specific equipments.

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- 5.3.7** Adequate packing of equipment shall be ensured to avoid any damage during transit. The packing materials used such as duralumin boxes, wooden boxes, shall be such that the equipments are not affected during the transport to the site.

5.4 CALIBRATION AND TEST METHODS

- 5.4.1** Up-to-date test/ calibration procedures (whether standard methods or internal procedures) shall be made available to all staff performing tests or calibrations at site. Procedures shall exist for the supply and updating of test/ calibration procedures required by staff working at site.
- 5.4.2** Where appropriate, the uncertainty of measurement will 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.

5.5 CERTIFICATES AND REPORTS

- 5.5.1** Procedures shall exist for recording and reporting all results obtained at site and shall be in line with the system operating in the permanent laboratory (where appropriate).
- 5.5.2** Results obtained from site tests/ calibrations shall be clearly identified on the test Reports/ calibration certificates, with the details of the location at which test/ calibration performed. Environmental conditions at the test/ calibration site shall also be clearly brought out in the certificate.

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APPENDIX A

1. APPLICATION

At the time of application, the laboratory must specifically identify those tests or calibrations (and personnel involved) that are performed at site, whether wholly or partly, including a complete description and identification of any mobile laboratory and its equipment. The laboratory must also identify themselves as an “Entity” or a part of a “permanent laboratory”, as defined in section III of this document. Laboratory shall mark the relevant facilities (mobile, site) as defined in QAI 402, QAI 202 (application forms) as well declare the staff responsible for site testing / calibration.

2. 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 at site, normally where testing/ calibration for a customer is performed. It shall also entail the assessment of the testing/ calibration competency of the site test/ calibration staff, with particular emphasis on those tests/ calibrations that can only be carried out at site.

The laboratories involved in site calibration/testing shall demonstrate the site calibration/ testing procedure, transportation of equipment for site calibration/ testing, verification of standards before and after calibration/ testing etc.

If the laboratory is performing calibration/ testing activities with same method/technique in its permanent facility as well as at site by same technique/procedure and using same/similar equipment; the assessment team witness the site calibration/ testing for the purpose of verification of site calibration/ testing procedures only and not necessarily for defining the CMC (for calibration)/ verifying testing capability.

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3. SCOPE OF ACCREDITATION

An accredited permanent laboratory which is also accredited for site testing/ calibration shall be issued one Scope of Accreditation indicating all tests/ calibrations within a particular discipline which they are accredited.

For the calibration laboratories, that are performing calibrations both at site and permanent facility by same methods / technique, the CMC shall be demonstrated in the permanent laboratory. The CMC demonstrated/ witnessed in the permanent laboratory is also valid for on-site calibrations with one of the remarks in the scope of accreditation as below:

- a. The laboratory is capable for site calibration however; the uncertainty at site depends on the prevailing actual environmental conditions and master equipment used.
- b. Only for Site Calibration
- c. Only for Permanent Laboratory

However, for the site calibration if the laboratory is using different method, technique other than that of permanent laboratory it shall be demonstrated for defining CMC and shall mentioned in the scope of accreditation separately.

Further, in exceptional cases like better CMC at site than the permanent one; the laboratory may be accredited for different CMC; for permanent and for site based on the request from the laboratory. In such cases (even if the laboratory is using same method/ technique for permanent and site facilities) laboratory shall demonstrate the CMC both at site and laboratory separately. However, it shall be ensured that CMCs shall be demonstrated within the boundaries of defined environmental conditions as specified in the relevant specific criteria of each discipline. In case the CMC for site are better than the permanent laboratory because of better environmental conditions etc.

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at the site, this statement to that effect shall be recorded at the scope of the laboratory.

An accredited site testing/ calibration entity shall be issued a certificate and scope of Accreditation specifying all site test/ calibrations for which they have been accredited. The accredited entity shall be identified on the certificate and scope by the address of the entities 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 and will be identified separately in the Scope of Accreditation.

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