



ACCLASS Guidance for Classification and Assessment of Multi-Site Laboratories

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1.0 INTRODUCTION

ISO/IEC 17025, “General Requirements for the Competence of Testing and Calibration Laboratories,” is used by ACLASS for all of its calibration and testing laboratory accreditations. Although ISO/IEC 17025 applies to laboratories which perform tests or calibrations in the main laboratory and at other locations, additional clarification is necessary. For the purposes of this document, the term “on-site” refers to tests or calibrations performed at the customer or a third party location.

This document applies to all applicant and accredited customers, where relevant.

2.0 DEFINITIONS

Multi-Site Laboratory: Laboratory whose activities are carried out at more than one location. These organizations may have satellite sites under the oversight of the main laboratory, may conduct on-site calibrations or tests (either in a customer facility or in a mobile laboratory deployed from the main laboratory), or may have more than one address for the main laboratory. A Multi-Site Laboratory is presumed to maintain a single accreditation that covers the main laboratory and all satellite and on-site operations.

Multi-Laboratory Corporation: Organization with more than one main laboratory whose corporate site may conduct some key activities (see definition below). Key activities are also carried out at each main laboratory. The corporate site may provide guidance and oversight or maintain quality documents but the individual laboratories operate on a day-to-day basis as autonomous organizations. Each laboratory applies for accreditation separately and is assessed and accredited as a separate entity, including a separate scope of accreditation for each laboratory. The individual laboratories may themselves be multi-site laboratories as defined above.

Main Laboratory: An organization which performs key activities including calibrations or tests and which operates on a day-to-day basis as an autonomous organization. The main laboratory may administer operations that include one or more satellite locations or on-site calibrations or tests.

Laboratory with Satellite Sites: An organization that is comprised of a main site and satellite site(s) that perform calibrations or tests at a remote permanent or semi-permanent location. The main site provides oversight of the satellite site activities.

Satellite Site: A permanent or semi-permanent remote site which operates as a subsidiary to the main laboratory. Calibrations or tests (and possibly other key activities) are conducted at the satellite site. Customers’ equipment or test samples are usually received at the satellite site and are not normally processed through the main laboratory. All test reports and calibration certificates issued by such a site must be issued from the main laboratory, but the location of the actual test or calibration must also be identified on the

report or certificate. The main laboratory provides oversight of all satellite site key activities.

Multi-Location Main Laboratory: An organization with more than one address. Calibrations or tests done at each address are distinct and one address must be designated as the main laboratory address for identification on the ACLASS certificate and scope of accreditation. The alternate address is considered another room of and is assessed as part of the main laboratory. All test reports and calibration certificates issued by such a laboratory must be issued from the main laboratory, but the location of the actual test or calibration must also be identified on the report or certificate.

On-Site Calibration or Testing: Calibrations or tests completed by the staff of the main or satellite laboratory at a customer or customer-designated location on a temporary basis. These calibration or tests may be conducted in a customer or customer-designated facility or in a mobile laboratory deployed from the main laboratory.

Multi-Site Assessment: An assessment conducted for multi-site organizations

Key Activities: Key activities include calibration or testing activities, test report or calibration certificate generation, policy formulation, process or procedure development, and, as appropriate, contract review, planning conformity assessments (internal audits), reviews, approvals and decisions on the results of conformity assessments.

3.0 REFERENCES

ISO/IEC 17025:2005 – “General Requirements for the Competence of Testing and Calibration Laboratories”

ISO/IEC 17011:2004 – “Conformity Assessments – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies”

4.0 ACCREDITATION PROCEDURE

Application

Upon submission of the application packet for accreditation, the customer must identify the address(es) of the laboratory and any satellite sites where accredited tests or calibrations are performed. On-site capability must also be identified. If the laboratory is part of a multi-laboratory corporation as defined above, the corporate site must apply for accreditation at the same time or must already be accredited by ACLASS.

ISO/IEC 17011, section 7.5.7, states that in addition to visiting the main site or head office during initial assessment, visits shall be made to all other premises of the laboratory from which one or more key activities are performed and which are covered by the scope of accreditation.

Multi-Laboratory Corporations

These laboratories will be assessed and accredited individually, including a separate scope of accreditation for each laboratory. If the quality management system is written and maintained by the corporate site, assessors will emphasize the laboratory's compliance to the corporate quality system. Deficiencies in the corporate quality system may also be identified during the assessment. Responses to all findings must be received within 30 days of the closing meeting where they are presented to the laboratory.

Individual laboratories may also be multi-site laboratories as defined in this document (i.e., have satellite sites, on-site capabilities, and/or multiple addresses).

Multi-Site Laboratories

Laboratories with Satellite Sites - Laboratory sites will be considered satellite sites if they meet the following requirements:

- The site is set up as a permanent or semi-permanent accessory laboratory.
- The main laboratory provides oversight of all satellite site key activities.
- The laboratory and the site(s) form one legal entity.
- The accreditation is for the entire organization¹.
- One management system exists covering the entire organization.
- Adequate procedures exist to protect the integrity of the reference standard and equipment used for each calibration and/or test.
- All calibration certificates or test reports are issued from the main laboratory.

All satellite sites will be visited during initial accreditation assessment and may be visited during surveillance and reassessment. As a minimum during initial assessments and reassessments, ACLASS assessors shall witness at least 33 % of the technicians from each satellite site^{2,3}. Additional technicians may be witnessed at surveillance visits.⁴ During each assessment, ACLASS assessors shall ensure that the following have been addressed by the main laboratory (or corporate site, if applicable) for each satellite site:

- a) Internal Audits
- b) Management Review
- c) Adherence to the Supplementary Requirements (see below section 5.0)
- d) PT/ILC Requirements for each site (depending on the extent of the site's capabilities on the scope of accreditation)

Multi-Location Main Laboratories: If a main laboratory operates out of more than one location, it may be classified as a multi-location main laboratory instead of being

¹ Only one certificate and scope of accreditation will be issued with the main laboratory's address.

² Full assessments are considered initial accreditation assessments and reassessments.

³ Records of all technicians from the corporate and satellite sites shall be made available.

⁴ ACLASS reserves the rights to require technician(s) from all sites to appear and be witnessed during surveillance visits.

considered a main laboratory with satellite site(s). If the customer equipment is processed through the main laboratory and the calibration or testing capabilities at the main laboratory and the other site are distinct, the site may be considered as part of (another room of) the main laboratory. In this case, the laboratory will be assessed as one entity and should be considered as such during the laboratory's internal audits, management reviews, and PT/ILC activities.

On-Site Calibrations and Tests: On-site activities introduce critical variables to the operational environment. This includes factors outlined in ISO/IEC 17025 such as environmental effects on tests or calibrations, site security, and transportation issues.

ACLASS assessors shall witness calibration or testing on-site during the accreditation assessment and all reassessments⁵. Extra costs may be incurred if the location of on-site calibration or testing adds additional time to the assessment. Simulation of these tests or calibrations shall be substituted only when visiting the available site(s) would be cost prohibitive, clearance would not be granted by the laboratory's customer(s), or unforeseen time constraints apply. Assessors are instructed that on-site witnessing is required only for laboratories that perform accredited tests or calibrations on-site.

Scope of Accreditation for Multi-Site Calibrations and Tests

The scope of accreditation shall indicate which parameters are available at satellite sites and on-site, if less than the full scope of accreditation. Locations of satellite sites or additional addresses (in the case of multi-location laboratories) will be identified in footnotes.

Applicant and accredited customers shall, when indicating on-site uncertainties on certificates, indicate: "Since field (on-site) conditions are typically more variable than those in the laboratory, larger measurement uncertainties are expected in the field than what is reported on the accredited scope."

5.0 SUPPLEMENTARY GUIDANCE FOR LABORATORIES

ACLASS Form 1, "ISO/IEC 17025 Checklist," identifies additional ACLASS requirements for laboratories with satellite sites and/or on-site capabilities.

⁵ ACLASS reserves the right to witness on-site calibration(s) and/or test(s) during surveillance visits.

Guidance for Classification of Multi-Site Laboratories

Revision History

Date	Description
June 15, 2005	Initial Draft – B. Hirt
July 1, 2005	Final review – K. Greenaway
October 11, 2005	Revisions to update in response to MRA obligations and to give further clarification to customer(s) and assessor(s) – K. Greenaway
October 31, 2005	Additional Review with some edits– Keith Greenaway and Bill Hirt
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September 21, 2009	Revisions to clarify and rename types of labs and provide additional guidance on requirements – T Burgess