Asia Pacific Laboratory Accreditation Cooperation

GUIDANCE FOR THE ASSESSMENT, REASSESSMENT, AND SURVEILLANCE OF "KEY ACTIVITIES" AT LABORATORIES WITH MULTIPLE LOCATIONS

PURPOSE

This document provides guidance on clauses 7.5.7 and 7.5.8 of ISO/IEC 17011 (*Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*).

AUTHORSHIP

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FURTHER INFORMATION

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1. INTRODUCTION

1.1 The purpose of this document is to provide guidance on clauses 7.5.7 and 7.5.8 of ISO/IEC 17011 (*Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*), which states that:

7.5.7 For initial assessments, in addition to visiting the main or head office, visits shall be made to all other premises of the CAB from which one or more key activities are performed and which are covered by the scope of accreditation.

NOTE: Key activities include: policy formulation, process and/or procedure development and, as appropriate, contract review, planning conformity assessments, review, approval and decision on the results of conformity assessments.

7.5.8 For surveillance and reassessment, where the CAB works from various premises, the accreditation body shall establish procedures for sampling to ensure proper assessment. All premises from which one or more key activities are performed should be assessed within a defined timeframe.

This guidance document is only applicable to laboratories accredited to ISO/IEC 17025.

1.2 ISO/IEC 17025 (*General Requirements for the Competence of Testing and Calibration Laboratories*), clause 1.1 states that "*This International Standard specifies the general requirements for the competence to carry out tests and/or calibrations…*" and clause 5 of this standard specifies the requirements for technical competence for the type of tests and/or calibrations the laboratory undertakes. Therefore, for a laboratory, a key activity – in addition to the management key activities listed in the note - also includes any activity that can impact the test result or calibration. This activity may include, but is not limited to:

- testing or calibration, in whole;
- a component of the testing or calibration, that is critical to the validity of the test result or calibration, including sampling when sampling is performed in accordance with ISO/IEC 17025, clause 5.7.

1.3 In those instances where a laboratory has physically set up other locations that are controlled by that same laboratory, and the other physical locations perform calibration and/or testing, in whole or in part, ISO/IEC 17011 clause 7.5.7 does apply. By doing any calibration and/or testing, the other physical location(s) must be deemed to be performing what are considered "key activities" and according to ISO/IEC 17011, clause 7.5.7 must be visited during the initial assessment.

1.4 Application of ISO/IEC 17011, clause 7.5.7 of is difficult in those instances where the actual testing and/or calibration is not occurring at a laboratory-controlled physical location. Examples include, but are not limited to, calibrations performed at customer locations, field-testing, and ambient air stations. Guidance for application of ISO/IEC 17011, clauses 7.5.7 and 7.5.8 in these and other scenarios is provided in this document.

2. DEFINITIONS

2.1 Base or Headquarters: A testing or calibration laboratory set up in a dedicated location for an indeterminate amount of time. This is the laboratory location (address) denoted on the scope of accreditation.

2.2 Fixed Location: A testing or calibration laboratory facility located in a different permanent building and at a different location from the base or headquarters.

2.3 Field Site: A location outside of a testing or calibration laboratory's base or headquarters where testing or calibration is performed by laboratory staff either from the base or headquarters or staff assigned to the location. The laboratory may be set-up for an indeterminate amount of time or just for the duration of the testing or calibration activities required for a time-limited contract. Examples of a field site include a Construction Materials laboratory set up at an airport construction site and a calibration laboratory set up under contract in support of a customer's manufacturing process. The laboratory may also be stationary or mobile.

2.4 Remote Site: A location outside of a testing or calibration laboratory's base or headquarters (including, but not limited to, a customer's premises). Testing or calibration may be performed by an automatic instrument (e.g., ambient air stations) or robot (e.g., remote calibration).

2.5 Field Representative: Trained laboratory staff going out with equipment to do testing and/or calibration.

2.6 Scope (of Accreditation): The official listing of the various tests, types of tests and/or test technologies, or the listing of the various parameters or types of calibration that the laboratory has been deemed competent to perform under their accreditation.

3. DETERMINING IF LOCATIONS FALL UNDER THE SAME SCOPE

3.1 Accreditation bodies should have policies and procedures in place to determine when laboratories with more than one location can be considered as being under one accreditation, and when two or more locations need to be considered as separate accreditations. For two or more locations to be considered as one accreditation, the following should be considered:

- If the base or headquarters has oversight of the quality management system of the fixed location, field site, or remote site, including but not limited to development of policies and procedures, and document control; and,

- If the base or headquarters has oversight of the technical operations of the fixed location, field site, or remote site.

If the accreditation body deems that two or more locations fall under the same scope, the following may be considered in the assessment and surveillance of the laboratory:

- how proficiency testing (PT) is distributed between technicians, sites, shifts, etc., where applicable; and,

- how traceability requirements are met, especially in those instances where a fixed location, field site, or remote site is in another economy.

4. ASSESSMENT, REASSESSMENT AND SURVEILLANCE

4.1 Once it is determined that two or more locations are covered under one scope of accreditation, the accreditation body should have policies and procedures in place to ensure that the assessment process conforms with ISO/IEC 17011, clauses 7.5.7 and 7.5.8. The following general categories provide suggested approaches to deal with these and related scenarios.

4.2 Testing and/or calibration, in whole or in part, occurring at a fixed location that is set up and controlled by the laboratory.

4.2.1 When testing and/or calibration, in whole or in part, is carried out at another fixed location that is covered by the base or headquarters accreditation, the fixed location(s) must be assessed during an initial visit, as per ISO/IEC 17011, clause 7.5.7. Procedures to make this determination, and records to back-up the decision should be available.

4.2.2 If management key activities such as contract review, policy formulation, etc…are occurring at the fixed location, with oversight from the base or headquarters, implementation of the activities needs to be assessed during the on-site visit.

4.2.3 If the fixed location is in another economy and a visit appears cost-prohibitive for the applicant laboratory, one approach may be that the assessment is carried out by another accreditation body that is signatory to the Asia Pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement (APLAC MRA) or International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA).

4.2.4 For surveillance visits and reassessments, the procedures should include sampling procedures to determine which fixed locations are reassessed, and the frequency of visits to ensure that all fixed locations are reassessed within a defined timeframe, as per ISO/IEC 17011, clause 7.5.8 In addition, surveillance of key activities may occur by other means (e.g., review of records).

4.2.5 It is possible that a fixed location does not carry out testing and/or calibration and is, *de facto*, an office. There still may be activities that are performed at this office or location which contribute to the testing outcomes, in which case a visit to the office is required. This should be explicitly considered before an accreditation body determines that a visit is not necessary.

4.3 Testing and/or calibration performed at field sites.

4.3.1 A field site – be it permanent or temporary, stationary or mobile – is similar to a fixed location in that testing and/or calibration is being carried out at the site. Hence, the field site is carrying out "key activities" and ISO/IEC 17011 clauses 7.5.7 and 7.5.8 applies. However, it is recognized that in some cases,

assessing each and every field site may be impractical, due to the nature of the test and/or calibration. It is incumbent on the accreditation body to have policies, procedures and criteria in place in order to make the decision as to whether a visit is required at a field site or not.

4.3.2 A consideration for mobile laboratories or short-term high-intensity work is to assess how the laboratory ensures the integrity of the equipment that is constantly being moved.

4.3.3 The accreditation body may also want to consider under what circumstances a laboratory designated as a field site may be deemed to be actually a base or headquarters. For example, a temporary field site that is continually extending its contract may in actuality have become a base or headquarters, and should be treated as such.

4.4 Field representatives performing testing and/or calibration.

4.4.1 The accreditation body should have procedures in place to determine the competence of the field representatives who are performing tests and/or calibrations. For initial accreditation, the accreditation body should have set criteria on determining which field representatives to witness. Options to perform the witnessing include, but are not limited to:

- assessors travelling to locations to witness the field representatives; or,
- having field representatives travel to the base/headquarters during the initial assessment.

4.4.2 If assessing a representative number of field representatives, the choice of field representatives to be witnessed by the accreditation body should be made by the accreditation body, and not the laboratory. The accreditation body's procedures to determine which field representatives to witness should take into account critical factors (e.g., new employees, the risks and the complexity of the testing and/or calibration activity, etc.). The accreditation body should keep a record of the analysis and/or rationale used to determine the number of field representatives that were chosen to complete the assessment.

4.4.3 Regardless of the number of field representatives to be witnessed, it should be cautioned that when requiring them to be at the base of headquarters during an assessment, demonstrations of testing and/or calibration performed under assessment-convenient conditions might not fully reflect the environmental conditions encountered in full-field conditions. Therefore, weaknesses in testing and/or calibration may not be identified.

4.4.4 For surveillance and reassessments, a representative number of field representatives should be present for interviews during the on-site assessment. Again, the accreditation body should have criteria on how field representatives are chosen, and in this scenario, past history of performance during the last (re)assessment could be taken into account. Alternatively, assessment could include ways other than witnessing performance to determine competence (e.g., review of records, telephone interviews, etc.). Regardless, the accreditation body should document the analysis and/or rationale used to make the decision on how competence was assessed. The accreditation body

requires objective evidence to make the determination that the field representatives are competent and capable of performing testing and/or calibration.

4.5 Remote Sites

4.5.1 The accreditation body should have procedures in place to assess that the laboratory has installed instrumentation correctly and that there are procedures in place to ensure that the data being generated at the remote site is valid. The accreditation body should have procedures to ensure that a representative number of sites were observed during the initial assessment and set up a process to assess them during subsequent visits (e.g., review of records). The accreditation body requires objective evidence to make the determination that the laboratory is competent and capable of performing testing and/or calibration remotely. For example, it would be expected that an accreditation body would assess such items as the integrity of the software used, information about the integrity of the hardware (if available), and/or the Internet protocol used.

5. REFERENCES

5.1 ILAC/IAF A5:04/2009 – IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Application of ISO/IEC 17011:2004