



Harmonised Procedures for Surveillance and Reassessment of Accredited Laboratories

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PREAMBLE

In the process of concluding multilateral agreements it is required that the participants in the agreement use similar procedures in the accreditation process. Such agreements impose stringent requirements because they are the basis for one-stop testing, calibration and accreditation in trade. The use of similar procedures means that participant accreditation bodies in the agreement provide the same degree of assurance as to the quality and competence of the laboratories they accredit.

In 1990 and 1993, two enquiries were conducted amongst accreditation bodies on surveillance and reassessment procedures. The results of the last enquiry were reported in ILAC '94 in Hong Kong. It was shown that differences existed between the various accreditation bodies in their perception of the meaning and function of surveillance and reassessment. Some accreditation bodies indicated that they apply proficiency testing as a substitute for surveillance.

As a consequence of this, differences existed in the conduct of surveillances and reassessment procedures. It also became clear that most accreditation bodies were willing to accept general procedures issued by ILAC. In the ILAC '94 General Assembly meeting it was decided that Working Group 1 of Committee 2 should prepare a guidance document on surveillance and reassessment of accredited laboratories.

PURPOSE

These guidelines provide a procedure for a harmonised approach to conducting surveillance and reassessment of accredited laboratories.

AUTHORSHIP

This document was prepared by a Working Group of ILAC Committee 2 and was endorsed for publication by Resolution No. 17/96 of ILAC '96. The convenor of the Working Group was Dr J G Leferink.

(NOTE: In many instances the word 'should' is used to provide flexibility. In few cases 'shall' is used because the requirement is fundamental in the context of the interpretations.)

1. INTRODUCTION

Laboratory accreditation is the best mechanism to provide assurance to customers on the quality and competence of the laboratory. International trade relies on certificates and reports issued by accredited laboratories. Confidence in accreditation is obtained by a transparent system of control over the accredited laboratories and an assurance given by the accreditation body that the accredited laboratory constantly fulfils the accreditation criteria. This assurance can be achieved through a mechanism of regular surveillance and reassessment visits enhanced, where appropriate, by other surveillance activities and regular participation in proficiency testing.

The main purpose of these guidelines is to achieve a comparable way of conducting surveillance and reassessment visits by laboratory accreditation bodies, especially those bodies that seek multilateral agreements through ILAC or through regional accreditation cooperations.

(NOTES

1. *These guidelines do not address which particular aspects of the quality system and technical operation should be checked. These aspects are described in the ISO/IEC Guides 25 and 58.*
2. *These guidelines do not address specific requirements of the accreditation body with respect to providing information on surveillance and reassessment to laboratories, and aspects of cooperation between laboratories and accreditation bodies in providing information to the accreditation body. These belong to the general documentation and rules of the accreditation body and should be publicly available before the accreditation process starts. These should never be a matter of negotiation prior to surveillance and reassessment.)*

2. TERMINOLOGY

- 2.1 Generally the terminology and definitions of ISO/IEC Guide 2, 25 and 58 apply in this document.
- 2.2 *Surveillance activities* are any activities undertaken by an accreditation body at any time to monitor the performance of accredited laboratories.
- 2.3 *Surveillance visits* are on-site visits to accredited laboratories or any other accredited facilities, undertaken by an accreditation body at any time to ensure that these laboratories operate in compliance with the accreditation requirements. Normally such visits are less comprehensive than an initial assessment visit.
- 2.4 *Surveillance assessment plans* are plans made by the accreditation body to schedule surveillance activities and visits, in particular based upon areas of competence, for individual laboratories between the initial assessment and the first reassessment or between reassessments.
- 2.5 *Reassessment* is a set of activities, always including a visit, undertaken by an accreditation body at regular intervals, to ensure that an accredited laboratory operates in compliance with the accreditation criteria.
- 2.6 *Vertical assessment* is a comprehensive assessment of all the aspects of one testing or calibration activity.
- 2.7 *Horizontal assessment* is focused on one particular aspect through the whole range of activities of the laboratory.
- 2.8 *Proficiency testing* is the determination of the laboratory's calibration or testing performance by means of interlaboratory comparison. Interlaboratory comparison is the Organisation, performance and evaluation of tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

3. SURVEILLANCE

- 3.1 The accreditation body shall have an established and documented program for carrying out periodic surveillance activities and surveillance visits at sufficiently close intervals to ensure that the accredited laboratory continues to comply with all accreditation criteria.
- 3.2 Surveillance activities include aspects such as:
- Enquiries from the accreditation body to the laboratory on aspects concerning the accreditation.
 - Declarations by the laboratory with respect to their operations.
 - Requests to the laboratory to provide documents and records (on paper or electronic media), including updates from quality manuals.
 - Assessing the laboratory's performance (including through proficiency testing).
 - Other means of monitoring the laboratory's testing and calibration performance.
- 3.3 Surveillance activities may be carried out at any time.
- 3.4 In addition to the above described surveillance activities, the accreditation body shall undertake surveillance or reassessment visits. Such on-site visits shall be conducted in a non-discriminatory way and be irrespective of the geographic location of the laboratory with respect to the location of the accreditation body.

(NOTE: Reassessment visits may always take the place of surveillance visits).

- 3.5 Interval between surveillance visits.
- 3.5.1 It is recommended that the first surveillance visit be carried out no later than 12 months from the date of initial accreditation.
- (NOTE: this interval is shorter than other surveillance intervals to avoid a commonly occurring problem that, after the initial assessment, there is a decrease in quality awareness in the laboratory.)*
- 3.5.2 It is recommended that subsequent surveillance visits be carried out no later than 18 months after the previous visit until at least the first reassessment. The preferred interval is 12 months.
- 3.5.3 In deciding on the interval of the surveillance visits and related activities at any particular laboratory after the first reassessment, the accreditation body may take into account the performance of that laboratory at previous visits. A minimum of three consecutive visits with good performance may lead to fewer surveillance visits in the future. When the performance of a laboratory deteriorates, the frequency of surveillance activities (and visits) would need to be increased.
- 3.5.4 An accreditation body may decide to conduct the surveillance visits without prior notice or with short notice only (less than two weeks) as a mechanism to lower the frequency of visits.

(NOTE: The accreditation body shall have predetermined criteria describing the relationship between the performance of the laboratory and the frequency of the surveillance visits and other surveillance activities.)

- 3.6 During a surveillance visit, elements of both the quality system and the testing and/or calibration activities should be assessed.
- 3.6.1 For the quality system, it is of particular importance to evaluate the internal audit and review. Which other elements of the quality system should be checked depends on various factors such as findings at previous visits, outstanding corrective action, performance in proficiency testing, personnel changes and other changes. All elements of the quality system should be assessed at least once between the initial assessment and reassessment or between two consecutive reassessments.
- 3.6.2 In practice, the competence of the laboratory does not have to be checked in all areas of accreditation at every surveillance visit. Changes in technical personnel and changes in equipment indicate that additional checking by the accreditation body is needed. The accreditation body should aim at assessing a representative sample of the accredited activities, covering all areas of competence, during the period between two reassessments or between initial accreditation and the first reassessment. It is therefore appropriate that the accreditation body makes a surveillance assessment plan for such a period. This is of special importance in multidisciplinary laboratories.
- 3.6.3 Extensions of the scope of accreditation, however, shall always be checked if new technical expertise is required.
- 3.6.4 The accreditation body should make use of horizontal and vertical assessment techniques.
- 3.7 At ordinary surveillance visits, the surveillance team shall have the competence to assess both the quality system components of ISO/IEC Guide 25 and the testing and/or calibration activities. If the surveillance is conducted by only one person, this person should have the ability to assess both the quality system components of ISO/IEC Guide 25 and the technical competence in one of the technical areas.
- 3.8 If an accreditation body receives any written claims or complaints creating doubts concerning an accredited laboratory, it will carry out surveillance activities (inquiries) or even extraordinary surveillance visits in the shortest possible time. Obviously these visits have a different meaning than the visits in section 3.5.4.

4. REASSESSMENT

- 4.1 In contrast to surveillance, reassessment is nearly as comprehensive as the initial accreditation and has the function of checking the laboratory's compliance with all the accreditation criteria, and assessing the coherence of the laboratory's quality system.
- 4.2 The accreditation body shall have an established and documented program for carrying out periodic reassessment visits to the accredited laboratory.
- 4.3 Reassessment visits should be conducted in a non-discriminatory way and be irrespective of the geographic location of the laboratory with respect to the location of the accreditation body.

- 4.4 The time interval between initial assessment and reassessment or between reassessments should not exceed 60 months (5 years). The recommended interval is 48 months (4 years).

(NOTE: Shorter intervals are applicable when an accredited body conducts only reassessment visits and no surveillance visits (see also section 3.4).)

- 4.5 All elements of both the quality system and a representative sample of the testing and/or calibration activities, covering all areas of competence, should be assessed during a reassessment visit, as in the initial assessment visit. Special attention is required for multidisciplinary laboratories as in section 3.6.2.

4.5.1 For the quality system, it is always important to evaluate the internal audit and review.

4.5.2 The accreditation body should make ample use of horizontal and vertical assessment techniques.

- 4.6 The reassessment team shall have the competence to assess both the quality system components of ISO/IEC Guide 25 and the full range of testing and/or calibration activities of the laboratory. A reassessment team should normally consist of at least two members.

- 4.7 The accreditation body should carefully consider the composition of the reassessment team. Preferably, new team members should be selected for each reassessment. This especially applies to the lead assessor.

5. PROFICIENCY TESTING

- 5.1 Where it is required of a laboratory to participate in proficiency testing, the performance of the laboratory as well as its corrective actions should be taken into account in conjunction with the findings of the surveillance and reassessment. Calibration laboratories are normally required to participate in proficiency testing.

(NOTE: It is important to distinguish between any type of interlaboratory comparison and specific interlaboratory comparisons set up for proficiency testing. Only well established proficiency testing schemes should be used in decisions on accreditation (see ISO/IEC Guide 43).)

- 5.2 Proficiency testing is a component of surveillance. It cannot replace surveillance visits as it usually only covers a small part of the scope for which the laboratory is accredited, and therefore cannot reflect the overall performance of the laboratory and its quality system.

(GENERAL NOTE: At the time of writing this document, ISO Guide 43 is being rewritten. The final text of ISO Guide 43 may influence the section on proficiency testing and the terminology section in this document.)