European co-operation for Accreditation

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Surveillance and Reassessment of Accredited Organisations

PURPOSE

In the process of concluding multilateral agreements it is required that the participants in the agreement use similar, if not identical procedures, in the accreditation process. Such agreements impose stringent requirements because they are the basis for one stop testing, calibration, inspection, certification and accreditation in trade.

Similar procedures mean that the procedures used give the same degree of assurance in the quality and competence of the accredited organisation.

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. This guide provides the procedure for a harmonised way of conducting surveillances and reassessments.

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This document has been prepared by EA.

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The text may be translated into other languages as required. The English language version remains the definitive version.

Further information
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1 INTRODUCTION

Accreditation is the best mechanism to provide assurance to customers on the quality and competence of a laboratory, inspection body or certification body. International trade relies on certificates and reports issued by accredited organisations. Confidence in accreditation is obtained by a transparent system of control over the accredited organisations and an assurance given by the accreditation body that the accredited organisation 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, in the case of laboratories, regular participation in proficiency testing.

The main purpose of this document is to achieve a comparable way of conducting surveillance and reassessment by accreditation bodies, especially those bodies that seek multilateral agreements under EA or other regional accreditation cooperations.

Note 1 This guide does not address which particular aspects of the quality system and operation should be checked. These aspects are described in the ISO/IEC and CEN/CLC standards and guides on conformity assessment.

Note 2 This guide does not address specific requirements of the accreditation body with respect to providing information on surveillance and reassessment to accredited organisations and aspects of co-operation between accredited organisations 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 and CEN/CLC standards and guides on conformity assessment 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 organisations.

2.3 Surveillance visits are on-site visits in the accredited organisations or any other accredited facilities, undertaken by an accreditation body at any time to ensure that these organisations operate in compliance with the accreditation requirements.

Normally such visits are less comprehensive than an initial assessment visit.

2.4 Surveillance assessment plan is a plan made by the accreditation body, in which it schedules surveillance activities and visits, in particular based upon areas of competence, for a particular organisation 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 accredited organisations operate in compliance with all the accreditation criteria.

2.6 Vertical assessment is a comprehensive assessment of all the aspects of one testing, calibration, inspection or certification activity.

2.7 Horizontal assessment is focused on one particular aspect through the whole range of activities of the accredited organisation.

2.8 Proficiency testing is the determination of the laboratory 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.

2.9 Witnessing is the on-site monitoring of the performance of an accredited organisation.

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 organisation continues to comply with all accreditation criteria.

3.2 Surveillance activities include aspects such as:

- Enquiries from accreditation bodies to accredited organisations on aspects concerning the accreditation.
- Declarations by accredited organisations with respect to their operations.
- Requests for documents and records (on paper or electronic media) from accredited organisations, including updates from quality manuals.
- Assessing the laboratories performance including proficiency testing.
- Witnessing the performance of accredited organisations.
- Assessing the implementation of the quality system (or part of the quality system) of accredited organisations

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 (Note: Reassessment visits may always take the place of surveillance visits). Such on-site visits shall be conducted in a non-discriminatory way and irrespective of the geographical location of the accredited organisation with respect to the office of the accreditation body.

3.5 Interval between surveillance visits.

3.5.1 The first surveillance visit should be carried out no later than 12 months from the date of initial accreditation.

3.5.2 Subsequent surveillance visits should be carried out no later than 18 months after the previous visit at least up to the first reassessment. A recommended interval is 12 months.

3.5.3 In deciding on the interval of the surveillance visits and activities at any particular accredited organisation after the first reassessment, the accreditation body may take into account the performance of that organisation in previous visits and activities.

3.5.4 An accreditation body may consider 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: Clearly the accreditation body shall have predetermined criteria describing the relation between the performance of the accredited organisation and the frequency of the surveillance visits and other surveillance activities.

3.6 During a surveillance visit elements of both the quality system and operational activities should be assessed.

3.6.1 For the quality system it is of particular importance to evaluate the internal audit and review. What other elements of the quality system should be checked depends on various factors such as findings at previous visits, outstanding corrections, 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 two consecutive reassessments.

3.6.2 The competence of the accredited organisation does not have to be checked in practice in all areas of accreditation at every surveillance visit. Changes in technical personnel and changes in equipment may 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 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 organisations.

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 and the operational activities. If the surveillance is conducted by only one person, this person should have the ability to assess both the quality system components and the competence in at least one of the accredited areas.

3.8 If an accreditation body receives any written claims or complaints creating doubts concerning an accredited organisation 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 3.5.4.

4 REASSESSMENT

option: replace by G.3.5.5. of the IAF Guide on ISO/IEC Guide 61

4.1 In contrast to surveillance, reassessment is nearly as comprehensive as the initial accreditation and has the function of a check of the compliance with all the accreditation criteria and of the coherence of the organisations' quality system.

4.2 The accreditation body shall have an established and documented program for carrying out periodic reassessment visits to the accredited organisations.

4.3 Reassessment visits should be conducted in a non discriminatory way and irrespective of the geographical location of the organisation with respect to the office of the accreditation body.

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

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

4.5 All elements of both the quality system and a representative sample of the operational 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 organisations as in 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 the criteria and the full range of operational activities of the accredited organisation.

5 PROFICIENCY TESTING

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

Remark: 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 can almost never replace surveillance visits because it can cover only a part of the scope for which the laboratory is accredited, and it cannot reflect the overall performance of the laboratory and its quality system.