



Publication

Reference

EA-3/08

EA Guidelines					
On the Application					
Of EN 45010					

PURPOSE

The text of this document has been produced by a working group in the International Accreditation Forum (IAF). The purpose of the document is to provide explanations with a view to harmonise the application of ISO/IEC Guide 61/EN 45 010 in the field of accreditation of certification/registration bodies. ISO/IEC Guide 61/EN 45 010 remains the authoritative document and in case of dispute concerning the application of this document, the individual accreditation bodies will adjudicate on unresolved matters.

Authorship

The publication has been written by a working group in the International Accreditation Forum (IAF).

Official language

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

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Issue date (IAF): 1 November 2003
Approval date (EA): 27 November 2003
Application date (EA/IAF): November 2004

Accreditation reduces risk for business and its customers by assuring them that accredited bodies are competent to carry out the work they undertake. Accreditation bodies which are members of the International Accreditation Forum, Inc. (IAF) are required to operate at the highest standard and to require the bodies they accredit to comply with appropriate international standards and IAF Guidance to the application of those standards.

Accreditations granted by accreditation body members of the IAF Multilateral Recognition Arrangement (MLA), based on regular surveillance to assure the equivalence of their accreditation programmes, allows companies with an accredited conformity assessment certificate in one part of the world to have that certificate recognised everywhere else in the world.

Therefore certificates in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment issued by bodies accredited by members of the IAF MLA are relied upon in international trade.

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Issue No 3

Prepared by: IAF Technical Committee

Approved by: IAF Members

Date: 21 September 2003

Issue Date: 1 November 2003

Application Date: 1 November 2004

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0.1. Introduction to IAF Guidance

0.1.1. ISO/IEC Guide 61:1996 is an International Standard which sets out criteria for bodies operating accreditation systems for certification/registration bodies. If such bodies are to be recognised at an international level as conforming to the standard some Guidance to the standard is necessary. These Guidance Notes provide it. One aim is to enable accreditation bodies to harmonise their application of the standards against which they are bound to assess certification/registration bodies. This is an important step towards mutual recognition of accreditation. It is hoped that this Guidance will also be useful to certification/registration bodies.

0.1.2. This document does not include the text of ISO/IEC Guide 61. Users must purchase that document from the appropriate Standards organization. Guidance, where it is offered, is identified with the letter “G”. The requirements against which conformity is determined are found in ISO/IEC Guide 61. This IAF Guidance does not create further requirements.

0.1.3. This Guidance will form the basis of mutual recognition agreements between accreditation bodies, and is considered necessary for the consistent application of ISO/IEC Guide 61. Members of the IAF Multilateral Agreement (MLA), and applicants for membership in that Agreement, will assess each others’ implementation of ISO/IEC Guide 61, and all of this Guidance is expected to be adopted by accreditation bodies as part of their general rules of operation.

0.1.4. The term “shall” is used throughout this document to indicate those provisions which, reflecting the requirements of ISO/IEC Guide 61, are mandatory. The term “should” is used to indicate guidance which, although not mandatory, is provided by IAF as a recognised means of meeting the requirements. Accreditation bodies whose systems do not follow the IAF Guidance in any respect will only be eligible for participation in MLAs or other forms of Multilateral Recognition Arrangements if they can demonstrate to the MLA that their solutions meet the relevant clause of ISO/IEC Guide 61 in an equivalent way.

0.1.5. An accreditation body shall at all times maintain its impartiality as required by clause 2.1. of ISO/IEC Guide 61. Nevertheless it shall be prepared to discuss this guidance and its interpretation with an applicant body, and, where appropriate, to respond to enquiries.

0.1.6. IAF has prepared this document as guidance on the application of ISO/IEC Guide 61. IAF has also prepared guidance documents for ISO/IEC Guides 62, 65 and 66.

APPLICATION GUIDANCE TO CLAUSES OF ISO/IEC GUIDE 61:1996

General Requirements For Assessment And Accreditation of Certification/registration Bodies

Section 1: General

1.1. Scope

1.2. References

1.3. Definitions

IAF Guidance to Clause 1.3. (G.1.3.1.)

G.1.3.1. The following definitions apply to the IAF Guidance in this document:

Assessment: All activities related to the accreditation of an organization to determine whether the organization meets all the requirements of the relevant clauses of ISO /IEC Guides 61, 62, 65 and/or 66, or other recognised normative documents, necessary for granting accreditation, and whether they are effectively implemented, including documentation review, accreditation assessment, preparation and consideration of the accreditation assessment report and other relevant activities necessary to provide sufficient information to allow a decision to be made as to whether accreditation shall be granted.

Logo: symbol used by a body as a form of identification, usually stylised. A logo may also be a mark.

Mark: legally registered trade mark or otherwise protected symbol which is issued under the rules of an accreditation body or of an applicant body indicating that adequate confidence in the systems operated by a body has been demonstrated in accordance with ISO/IEC Guides 61, 62, 65 or 66 or that relevant management systems, products or individuals conform to the requirements of a specified standard.

Nonconformity: The absence of, or the failure to implement and maintain, one or more quality management system requirements of the reference standard, or a situation which would, on the basis of available objective evidence raise significant doubt as to the credibility of the certificates issued by the applicant body.

The applicant body is free to define different grades of deficiency and areas for improvement (e.g. Major and Minor Nonconformities, Observations, etc.). However all deficiencies which equate to the above definition of nonconformity should be dealt with as laid down in G.2.3.3. and G.3.5.1.

MLA: A multilateral mutual recognition agreement group of accreditation bodies, which accepts members on the basis of perceived equivalence of accreditations, established by means of peer evaluation, normally in the context that the accreditation body concerned is a member in good standing in such a group.

Section 2: Requirements for Accreditation Bodies

2.1. Accreditation body

2.1.1. General provisions

IAF Guidance to Clause 2.1.1. (G.2.1.1. - G.2.1.3.)

G.2.1.1. The provision “if an explanation is required” in clause 2.1.1.3. of ISO/IEC Guide 61 shall be applied by limiting such documents to those recognised by IAF or an MLA of accreditation bodies.

G.2.1.2. Accreditation bodies shall not practice any form of discrimination, such as national origin, nationality of employees, or hidden discrimination by speeding up or delaying applications.

G.2.1.3. Clause 2.1.1.2. of ISO/IEC Guide 61 requires accreditation bodies to make their services available to all applicants. They may, however, provide an accreditation service which excludes areas of activity where the accreditation bodies is not qualified to accredit, or has elected not to provide service to all applicant bodies in a particular category. For example, an accreditation body may, in so far as the law permits, limit its service to applicants operating in a defined geographic region, or it may limit its service to applicant bodies operating within a particular technical sector.

2.1.2. Organization

IAF Guidance to Clause 2.1.2. (G. 2.1.4. to G.2.1.27.)

G.2.1.4. Accreditation shall only be carried out by a body which is a legal entity as referenced in clause 2.1.2.d) of ISO/IEC Guide 61. If the accreditation activities are carried out by a legal entity which is part of a larger organization, the links with other parts of the larger organization shall be clearly defined and should demonstrate that no conflict of interest exists, see the guidance G.2.1.18., G.2.1.19. and G.2.1.20. Relevant information on activities performed by the other parts of the larger organization shall be documented. In such a situation, the structure of the entire legal entity may be subject to independent assessment, for example by any MLA in which the accreditation body participates, in order to pursue specific audit trails and/or review records relating to the specific accreditation activities being evaluated. The part of the legal entity that forms the actual accreditation body may operate under a distinctive name (and shall have a distinctive logo). The decisions of the accreditation body shall not be subject to approval by another body.

For the purposes of clause 2.1.2.d) of ISO/IEC Guide 61, accreditation bodies which are part of government, or are government departments, will be deemed to be legal entities on the basis of their governmental status. Such bodies’ status and structure shall be formally documented and the body shall conform to all the requirements of ISO/IEC Guide 61.

G.2.1.5. Impartiality and independence of the accreditation body should be assured at three levels -

1. Strategic and Policy;
2. Decisions on Accreditation;
3. Assessment.

The guidance to clause 2.1.2 of ISO/IEC Guide 61 is intended to provide for impartiality and independence at all three levels.

G.2.1.6. Impartiality, as required by clause 2.1.2.a) of ISO/IEC Guide 61 can only be safeguarded by a structure, as required by clause 2.1.2.e) of ISO/IEC Guide 61, that enables “the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the accreditation system”.

G.2.1.7. The structure required by ISO/IEC Guide 61, clause 2.1.2.e) for the safeguarding of impartiality shall be separate from the management established to meet the requirements of ISO/IEC Guide 61 clause 2.1.2.c), unless the entire management function is performed by a committee or group that is constituted to enable participation of all parties as required by ISO/IEC Guide 61, clause 2.1.2.e).

G.2.1.8. Conformance with clause 2.1.2.e) of ISO/IEC Guide 61 has the effect of counteracting any tendency on the part of the controlling authority (such as government or an industry body) under whose auspices an accreditation body operates to influence the accreditation body in a way which could prevent the consistent technically objective provision of its service. The accreditation body shall have documented evidence that it is in full control of accreditation decisions, and that no one party has the ability to unduly influence the decisions of the accreditation body.

G.2.1.9. Clause 2.1.2.e) of ISO/IEC Guide 61, therefore, requires that the documented structure of the accreditation body provides for the participation of all the significantly concerned parties. This should normally be through some kind of committee. This structure shall be formally established at the highest level within the organization either in the documentation that establishes the accreditation body's legal status or by some other means that prevents it being changed in a manner that compromises the safeguarding of impartiality. Any change in this structure should take into account advice from the committee, or equivalent, referred to in Clause 2.1.2 e).

G.2.1.10. Application of ISO/IEC Guide 61, clause 2.1.2.e) requires judgement on whether all parties significantly concerned in the system are able to participate. What is essential is that all identifiable major interests should be given the opportunity to participate, and that a balance of interests, where no single interest predominates is achieved. The members of the committee should be chosen from, at least, among representatives of conformity assessment experts, certification bodies, manufacturers or other organizations, and users. Where one sector (eg Government, industry etc) provides more than one individual to represent different aspects of the interest, the fact that they come from the one sector will deem them to constitute a single interest. For practical reasons there may be a need to restrict the number of persons on the committee.

G.2.1.11. The management responsible for the various functions described in clause 2.1.2.c) of ISO/IEC Guide 61 should provide all the necessary information, including the reasons for all significant decisions and actions, and the selection of persons responsible for particular activities, in respect of accreditation, to the committee or equivalent referred to in clause 2.1.2.e) of ISO/IEC Guide 61, (so long as the latter function is performed separately - see G.2.1.7. above) to enable the accreditation body to ensure proper and impartial accreditation. If the advice of the committee or equivalent is not respected in any matter by the management, the committee or equivalent shall take appropriate measures, which may include informing the relevant Management Committee of any MLA in which the accreditation body participates.

G.2.1.12. If the accreditation body and an applicant or accredited body are both part of government, the two bodies shall not directly report to a person or group having operational responsibility for both. The accreditation body shall, in view of the impartiality requirement, be able to demonstrate how it deals with a case where both itself and an applicant body are part of government. The accreditation body shall demonstrate that the applicant body receives no advantage and that impartiality is assured.

G.2.1.13. The requirement for financial stability referred to in Clause 2.1.2i) requires the accreditation body to demonstrate that it has a reasonable expectation of being able to continue to provide the service in accordance with its contractual obligations.

G.2.1.14. If the decision to issue or withdraw accreditation in accordance with clause 2.1.2.n) of ISO/IEC Guide 61 is taken by a committee comprising, among others, representatives from one or more accredited applicant bodies, or their related bodies, the operational procedures of the accreditation body should ensure that these representatives do not have a significant influence on decision making. This can e.g. be assured by the distribution of voting rights or some other equivalent means.

G.2.1.15. Clause 2.1.2.o) of ISO/IEC Guide 61 addresses two separate requirements. First, the accreditation body shall not provide the services identified in sub-paras 1), 2) and 3) of that clause where a conflict of interest might occur. Secondly, although there is no specific restriction on the services or activities a related body may provide, these shall not affect the confidentiality, objectivity or impartiality of the accreditation body.

G.2.1.16. Accreditation bodies can carry out the following duties without them being considered as causing a potential conflict of interest:

- a) accreditation including information meetings, planning meetings, examination of documents, assessment and follow up of nonconformities;
- b) arranging and participating as a lecturer in training courses, provided that where these courses relate to quality assurance, product certification, management systems, personnel, auditing or assessment, they should confine themselves to the provision of generic information and advice which is freely available in the public domain, i.e. they should not provide specific advice to an individual organization in relation to the activities of that organization;
- c) making available or publishing on request information on the basis for the accreditation body's interpretation of the requirements of the assessment standards;
- d) activities prior to assessment aimed solely at determining readiness for assessment; but such activities shall not result in the provision of recommendations, assistance or advice to the applicant body, and the accreditation body should ensure that such activities do not contravene these requirements;
- e) adding value during assessments and surveillance visits, e.g., by identifying opportunities for improvement, as they become evident, during the assessment without recommending specific solutions;
- f) training its own staff and assessment personnel, and/or the personnel of other accreditation bodies or developing accreditation bodies, in matters related to the accreditation function.

G.2.1.17. Activities under clause 2.1.2.o) of ISO/IEC Guide 61 by a related body and accreditation should never be marketed together, and nothing should be stated in marketing material or presentation, written or oral, to give the impression that the two activities are commercially linked. Nothing should be said or implied by an accreditation body that would suggest that accreditation would be simpler, easier or less expensive if any specified personnel, consultancy or training services were used. Accreditation must be seen by all parties in the market to be and remain impartial.

G.2.1.18. A related body, as referred to in clause 2.1.2.o) of ISO/IEC Guide 61, is one which is linked to the accreditation body by common ownership or directors, contractual arrangement, common elements in the name, informal understanding or other means such that the related body has a vested interest in the outcome of an assessment or has a potential ability to influence the outcome of an assessment. Where both the accreditation body and the applicant body are part of the same government they shall be regarded as related bodies.

G.2.1.19. The accreditation body should analyse and document the relationship with such related bodies to determine the possibilities for conflict of interest with provision of accreditation and identify those bodies and activities that could, if not subject to appropriate controls, affect confidentiality, objectivity or impartiality.

G.2.1.20. Accreditation bodies shall manage their accreditation and any other activities so as to eliminate actual or perceived conflict of interest and minimise any identified risk to impartiality. All potential sources of conflict of interest, whether they arise from within the accreditation body or from the activities of related bodies shall be identified and documented. These may be subject to independent assessment, for example by any MLA in which the accreditation body participates. This may include, to the extent practical and justified, pursuit of audit trails to review records of both the accreditation body and its related body for the activity under consideration. In considering the extent of such audit trails account should be taken of the accreditation body's history of impartial accreditation. If evidence of failure to maintain impartiality is found, there may be a need to extend the audit trail back into related bodies to provide assurance that control over potential conflicts of interest has been re-established. The accreditation body shall ensure that all assessment sub-contractors or external assessors or technical experts advise it of any potential conflict of interest either in their own relationships or the relationship of related bodies with an applicant certification/registration body or its competitors. The accreditation body shall ensure that personnel actually used in any accreditation assessment are free from actual or potential conflicts of interest.

G.2.1.21. The requirements of clause 2.1. and clause 2.2.3. of ISO/IEC Guide 61 mean that people who have had an involvement, within the last two years, with an applicant certification/registration body, with one of its competitors, or with a body related to the applicant body, including acting in a managerial capacity or acting as an assessor, should not be employed to conduct an assessment as part of the accreditation process. Situations such as an employer's involvement or previous involvement with the applicant certification/registration body being assessed or any of its competitors may present individuals involved in any part of the accreditation process with a conflict of interest. The accreditation body has a responsibility to identify and evaluate such situations and to assign responsibilities and tasks so as to ensure that impartiality is not compromised.

G.2.1.22. The senior executive, staff and/or personnel mentioned in clause 2.1.2. of ISO/IEC Guide 61 may not necessarily be full-time personnel, but their other employment shall not be such as to compromise their impartiality.

G.2.1.23. The accreditation body should require all assessment sub-contractors or external assessors to give undertakings regarding the marketing of any consultancy services equivalent to those required by guidance G.2.1.17.

G.2.1.24. The accreditation body should be responsible for ensuring that neither related bodies, nor sub-contractors, nor external assessors operate in breach of the undertakings that they have given. It should also be responsible for implementing appropriate corrective action in the event such a breach is identified.

G.2.1.25. The accreditation body should be independent from the body or bodies (including any individuals) which provide the internal audit of the applicant body's quality management system subject to accreditation.

G.2.1.26. An assessor should explain the assessment findings and/or clarify the requirements of the assessment standard during the assessment and /or at the closing meeting but shall not give prescriptive advice or consultancy as part of an assessment.

G.2.1.27. The policies and procedures referred to in clause 2.1.2.p) should ensure that all disputes and complaints are dealt with in a constructive and timely manner. Where operation of such procedures has not resulted in the acceptable resolution of the matter or where the proposed procedure is unacceptable to the complainant or other parties involved, the accreditation body's procedures shall provide for an appeals process. This appeals procedure shall include provision for the following:

- a) the opportunity for the appellant to formally present its case;
- b) provision of an independent element or other means to ensure the impartiality of the appeals process;
- c) provision to the appellant of a written statement of the appeal findings including the reasons for the decisions reached.

The accreditation body shall ensure that all interested parties are made aware, as and when appropriate, of the existence of the appeals process and the procedures to be followed.

2.1.3. Subcontracting

IAF Guidance to Clause 2.1.3. (G.2.1.28. to G.2.1.30.)

G.2.1.28. An accreditation body may issue accreditations on the basis of an assessment carried out by another body provided that the agreement with the subcontracted body requires it to conform to all the relevant requirements of ISO/IEC Guide 61 and of this document and, in particular, the requirements of clause 2.2. of ISO/IEC Guide 61. Evaluation of the assessment report and the decision on accreditation shall be made only by the accreditation body itself, and it shall satisfy itself that the assessments carried out by the subcontracted body give the same confidence as its own assessments. Where joint assessments are undertaken, each accreditation body shall satisfy itself that competent accreditation assessors have satisfactorily undertaken the whole of the assessment.

G.2.1.29. Where an accreditation body issues certificates in accordance with Guidance G.2.1.28., it shall have procedures that ensure conformity with all relevant clauses of this document by subcontracted bodies.

G.2.1.30. The requirement in clause 2.1.3.c) of ISO/IEC Guide 61 does not mean that the consent of the body under assessment is required in case of subcontracting of administrative activities such as typing.

2.1.4. Quality system

IAF Guidance to Clause 2.1.4. (G.2.1.31. to G.2.1.32.)

G2.1.31. The requirement in Clause 2.1.4.2 for an accreditation body to designate a person with direct access to its highest executive level does not preclude the chief executive from assuming this role and responsibility for a) and b)

G2.1.32. The description required by clause 2.1.4.3.e) of ISO/IEC Guide 61 should include an indication of which party or parties each member of a committee (e.g. a Board) is representing.

2.1.5. Conditions for granting, maintaining, extending, reducing, suspending and withdrawing accreditation

IAF Guidance to Clause 2.1.5. (G.2.1.33. to G.2.1.35.)

G.2.1.33. The accreditation body shall maintain procedures on actions to be taken when an applicant body informs the accreditation body that it intends to certify/register in new areas, or in specialised fields (parts of scope sectors) not previously notified to the accreditation body, and it intends to seek accreditation for that part or sector. Procedures shall indicate what steps the accreditation body would take if approached for accreditation in non-active areas, and shall make adequate provision for the acquisition of the necessary knowledge and experience before such applications are accepted.

G.2.1.34. Accreditation shall not be granted until there is sufficient evidence to demonstrate that the applicant body's arrangements for management review and internal audit have been implemented, are effective and will be maintained.

G.2.1.35. The accreditation body should define the consequences of suspension and of withdrawal. Suspension of accreditation need not be published by an accreditation body. However, withdrawal of accreditation shall result in, as a minimum, an amendment to the directory referenced in Clause 2.1.7.1.g). of ISO/IEC Guide 61. But also note the requirements in Clause 3.1.1.2.e) of ISO/IEC Guide 61.

2.1.6. Internal audits and management reviews

IAF Guidance to Clause 2.1.6. (G.2.1.36.)

G.2.1.36. Clause 2.1.6. of ISO/IEC Guide 61 does not mention a specific period in which at least one complete internal audit and one management review of the accreditation body's quality system should take place. The period selected by the accreditation body shall relate to the degree of conformity with the requirements of ISO/IEC Guide 61, as found in internal audits and reviews. Complete internal audits followed by management reviews of the accreditation body's quality system should be carried out at least once each year.

2.1.7. Documentation

IAF Guidance to Clause 2.1.7. (G.2.1.37.)

G.2.1.37. The description of the means by which the accreditation body obtains financial support referred to in Clause 2.1.7.1.d) of ISO/IEC Guide 61 should be sufficient to show whether or not the body can retain its impartiality.

2.1.8. Records

2.1.9. Confidentiality

IAF Guidance to Clause 2.1.9. (G.2.1.38.)

G.2.1.38. The requirement as to confidentiality includes anyone who might gain access to information which the accreditation body should keep confidential. Subcontracted personnel shall be required to keep all such information confidential, particularly from fellow employees and from their other employers.

2.2. Accreditation body personnel

2.2.1. General

IAF Guidance to Clause 2.2.1. (G.2.2.1. to G.2.2.4.)

G.2.2.1. The accreditation body shall have the required resources under its own control in terms of accreditation personnel, expertise and equipment to perform assessment, accreditation and surveillance of the applicant body's operations for conformity to the requirements of the relevant standard.

G.2.2.2. The term "resources under its own control" can include individual accreditation assessors who work for the accreditation body on a contract basis, or other external resources. The accreditation body shall be in a position to manage, control and be responsible for the performance of all its resources and maintain comprehensive records controlling the suitability of all the staff it uses in particular areas, whether they are employees, employed on contract or provided by external bodies.

G.2.2.3. The management of the accreditation body shall have the resources to enable it to determine whether or not, and procedures to ensure that, individual accreditation assessors are competent for the tasks they are required to perform within the field of accreditation in which they are operating. The competence of accreditation assessors may be established by verified background experience, specific training or briefing. The accreditation body should be able to communicate effectively with all those whose services it uses.

G.2.2.4. Accreditation bodies shall have personnel competent to:

- a) select and verify the competence of accreditation assessors
- b) brief and train accreditation assessors
- c) decide on the granting, maintaining, withdrawing, suspending, extending, or reducing of accreditations
- d) set up and operate an appeals, complaints and disputes procedure.

2.2.2. Qualification criteria for auditors and technical experts

IAF Guidance to Clause 2.2.2.2. and 2.2.2.3. (G.2.2.5.)

G.2.2.5. These clauses make reference to ISO 10011 Parts 1 and 2. This series of standards has now been superseded by ISO 19011. For the applicable requirements the term “should” in ISO 19011 shall be interpreted as described in the fourth paragraph of the “Introduction to IAF Guidance” (0.1.4 above).

Note: It is important to remember that ISO 19011 sets out guidelines for a wide range of audit situations, so some of the guidelines are inapplicable to third party assessment of certification/registration bodies.

2.2.3. Selection procedure

2.2.3.1. Selection of auditors and technical experts, in general

IAF Guidance to Clause 2.2.3.1. (G.2.2.6.)

G.2.2.6. Clause 2.2.3.1.b) requires the accreditation body to assess and monitor the conduct and performance of assessors and technical experts. Such assessment and monitoring should include witnessing the activities of the assessors and technical experts on-site.

2.2.3.2. Assignment for a specific assessment

IAF Guidance to Clause 2.2.3.2. (G.2.2.7. to G.2.2.10.)

G.2.2.7. Accreditations and scope extensions shall not be issued or granted until adequate resources can be deployed to conduct accreditation assessments meeting the requirements of ISO/IEC Guide 61 and this guidance. The accreditation body's procedures shall ensure that personnel employed to assess applicant bodies are competent in the field in which the applicant body operates

G.2.2.8. The assessment team, deployed in each case by an accreditation body to conduct an assessment of an applicant or accredited body, needs an understanding of the issues relating to the size, complexity, field of activity and business considerations of the body being assessed, and what factors, general to the sectors in which the body operates, are essential to ensure that certificates issued are credible. Each assessment team shall have a general understanding and background in the field in which the certification/registration body operates. This may include sector schemes. It shall be able to determine whether or not a particular body adequately conforms with the requirements of ISO/IEC Guides 62, 65 and/or 66, or other recognised normative document, and that confidence in the certificates it issues can be assured.

G.2.2.9. In certain instances, particularly where there are critical requirements and special procedures, the background knowledge of the assessment team may be supplemented by briefing, specific training or experts in attendance. The accreditation body may attach technical experts to their assessment teams. If an accreditation body does use technical experts, its systems shall include details of how technical experts are selected and how their technical knowledge is assured on a continuing basis. The accreditation body may rely on outside help, for example, from industry or professional institutions.

G.2.2.10. The requirements of clause 2.2.3.2. of ISO/IEC Guide 61 have a bearing on the employment of personnel. IAF considers that individuals involved in the accreditation process, including those acting in a managerial capacity, shall not have been involved in any consulting activities towards the applicant body in question, or any of its competitors or related bodies, within the last two years. Situations such as an employer's involvement or previous involvement with the applicant body being assessed, its related bodies, or its competitors, may present individuals involved in any part of the accreditation process with a conflict of interest. The accreditation body has a responsibility to identify and evaluate such situations and to assign responsibilities and tasks so as to ensure that there is no conflict of interest.

2.2.4. Contracting of assessment personnel

2.2.5. Assessment personnel records

2.2.6. Procedures for assessment teams

2.3. Decision on accreditation

IAF Guidance to Clause 2.3. (G.2.3.1. – 2.3.4.)

G.2.3.1. The information gathered during the accreditation process should be sufficient:

- a) for the accreditation body to be able to take an informed decision on accreditation;
- b) for traceability to be available in the event, for example, of an appeal ;
- c) to ensure continuity, for example for planning for the next assessment (possibly by a different team).

The information referred to in clause 2.3.1. of ISO/IEC Guide 61 is not necessarily limited to the information contained in the assessment report produced in accordance with clause 3.4.1.b) of ISO/IEC Guide 61, but may also include information gathered from other elements of the accreditation process (eg application, documentation review etc).

G.2.3.2. The entity, which may be an individual, which takes the decision on granting / withdrawing an accreditation within the accreditation body, should include a level of knowledge and experience sufficient to evaluate the assessment processes and associated recommendations made by the assessment team.

G.2.3.3. Accreditation shall not be granted until all nonconformities as defined in guidance G.1.3.1. have been corrected and the corrective action verified.

G.2.3.4. All accreditation documents shall identify the term for which the accreditation is valid.

2.4. References to accredited status

IAF Guidance to Clause 2.4. (G.2.4.1. to G.2.4.2.)

G.2.4.1. A certificate of accreditation shall state the name of the accreditation body that issued it. The scope of the accreditation of the applicant body shall be clearly identified.

G.2.4.2. The accreditation body should have documented procedures for the use of its mark, and for the procedures it is to follow in case of misuse, including false claims as to accreditation and false use of accreditation body marks. The mark of the accreditation body shall be registered or legally protected to ensure that the accreditation body has exclusive control over its use. Notwithstanding clause 2.1.1. of ISO/IEC Guide 61, misuse of an accreditation mark could be grounds for declining accreditation of an applicant body.

2.5. Change in the accreditation requirements

2.6. Appeals, complaints and disputes

IAF Guidance to Clause 2.6. (G.2.6.1. to G.2.6.3.)

G.2.6.1. Personnel, including those acting in a managerial capacity, should not be employed to investigate any appeal, complaint or dispute if they have been directly involved in activities as described under clause 2.1.2.o) of ISO/IEC Guide 61 towards the body in question, or any body related to that body (see G.2.1.18.), within the last two years.

G.2.6.2. Complaints represent a source of information as to possible nonconformity. On receipt of a complaint the accreditation body shall establish, and where appropriate take action on, the cause of the complaint, including any predetermining (or predisposing) factors within its own or an applicant body's management system.

G.2.6.3. The accreditation body should use such investigation to develop corrective action, which should include measures for:

- a) restoring conformity to ISO/IEC Guide 61 as quickly as practicable;
- b) preventing recurrence;
- c) assessing the effectiveness of the corrective measures adopted.

2.7. Access to records of appeals, complaints and disputes

IAF Guidance to clause 2.7. (G.2.7.1. – G.2.7.4.)

G.2.7.1. This clause deals only with complaints received by the accredited body (certification/registration body), not by the accreditation body.

G.2.7.2. During surveillance assessments accreditation bodies should check where any such nonconformity or failure to meet the requirements of the standard is revealed, that the accredited body has investigated its own systems and procedures and taken appropriate corrective action.

G.2.7.3. The accreditation body should satisfy itself that the accredited body is using such investigations to develop corrective action, which should include measures for

- a) notification to appropriate authorities if required by regulation;
- b) restoring conformity as quickly as practicable;
- c) preventing recurrence;
- d) evaluating and mitigating any adverse management system aspects and their associated impacts;
- e) ensuring satisfactory interaction with other components of the management system;
- f) assessing the effectiveness of the corrective measures adopted.

G.2.7.4. The implementation of the corrective action should not be deemed to have been completed until its effectiveness has been demonstrated and the necessary changes made in the procedures, documentation and records.

Section 3: Requirements for assessment

3.1. Application for accreditation

3.1.1. Information on the procedure

IAF Guidance to Clause 3.1.1. (G.3.1.1.)

G.3.1.1 The accreditation body shall require its accredited bodies to have procedures to ensure that the information supplied to the accreditation body is kept up-to-date.

3.1.2. The application

3.2. Preparation for assessment

IAF Guidance to Clause 3.2. (G.3.2.1. to G.3.2.2.)

G.3.2.1. The review mentioned in clause 3.2.1. of ISO/IEC Guide 61 is a preliminary review, preceding the review meant in the rest of Section 3.

G.3.2.2. The reference to the language of the applicant in clause 3.2.1.c) of ISO/IEC Guide 61 does not exclude the possibility of using interpreters and other individuals as specialist advisers to the assessment team.

3.3. Assessment

IAF Guidance to Clause 3.3. (G.3.3.1. to G.3.3.3.)

G.3.3.1. Accreditation bodies shall allow accreditation assessors sufficient time to undertake all activities relating to an assessment or re-assessment. The time allocated should be based on such factors as the size of the organization, number of locations and the scope of the accreditation.

G.3.3.2. The accreditation body shall require the body subject to the accreditation assessment to conform to the decision of the accreditation assessment team as to the assessors of the applicant body (chosen from those the applicant body deems competent in a particular scope sector) it wishes to see in action.

G.3.3.3. In witnessing the on-site activities of the applicant body, as required by clause 3.3.2. of ISO/IEC Guide 61, the accreditation body should if possible witness at least one initial assessment or a re-assessment. If it is not possible to witness an initial assessment or re-assessment then a minimum of two surveillance assessments should be witnessed, in which case the witnessed surveillance should cover key requirements of the assessment standard including at least process control and, where applicable, design and development.

3.4. Assessment report

IAF Guidance to Clause 3.4. (G.3.4.1. – G.3.4.4.)

G.3.4.1. Clause 3.4.1.b) of ISO/IEC Guide 61 requires more than a generic summary statement. The report of findings provided to the accreditation body shall be of sufficient detail to facilitate and support an accreditation decision and should include:-

- Areas covered by the assessment (eg. areas of the accreditation requirements and locations/units/departments/processes of the certification/registration body subject to assessment) including significant audit trails followed;
- Observations made, both positive (eg. noteworthy features) and negative (eg. potential non conformities);
- Report (details) of any nonconformities identified supported by objective evidence.

Completed questionnaires/checklists/observation logs/assessor notes might form an integral part of the report that covers the above. If these methods are used, these documents shall be submitted to the accreditation body as evidence to support the accreditation decision.

G.3.4.2. The first element of clause 3.4.1.e5) of ISO/IEC Guide 61 requires the report to contain comments on the conformity of the applicant body with the accreditation requirements. This can be satisfied by a brief ‘written’ statement summarising the overall findings (conclusion) of the assessment and a statement of judgement as to the body’s capability of systematically meeting the requirements.

G.3.4.3. The final element of clause 3.4.1.e.5.) of ISO/IEC Guide 61 “and, where applicable, any useful comparison with the results of previous assessment of the body”, does not apply to initial assessments but is relevant only to corrective action follow up visits, partial reassessments and surveillance visits.

G.3.4.4. In addition to the requirements for reporting in clause 3.4.1.e) of ISO/IEC Guide 61, this information should cover:

- The degree of reliance that can be placed on the internal audit;
- A summary of the most important observations, positive as well as negative, regarding the implementation and effectiveness of the applicant’s procedures and system;
- The conclusions reached by the assessment team.

3.5. Surveillance and reassessment procedures

IAF Guidance to Clause 3.5. (G.3.5.1. to G.3.5.11.)

G.3.5.1. Accreditation bodies shall have clear procedures laying down the circumstances and conditions in which accreditations will be maintained. If on surveillance or re-assessment, nonconformities, as defined in G.1.3.1., are found to exist, such nonconformities shall be effectively corrected within a time agreed by the accreditation body. If corrective action is not made within the time agreed accreditation shall be reduced, suspended or withdrawn. The time allowed to implement corrective action should be consistent with the severity of the nonconformity and the risk.

G.3.5.2. Surveillance undertaken by the accreditation body shall give assurance that the bodies it accredits continue to conform to the requirements of ISO/IEC Guides 62, 65 and/or 66 or other recognised normative document. The accreditation body shall have the facilities and procedures to enable it to achieve this.

G.3.5.3. The surveillance programme of the accreditation body should be determined by the accreditation body, taking into account the internal audit programme and the reliability that can be attributed to it, specific dates for visits may be agreed with the accredited body.

G.3.5.4. The surveillance activities shall be subject to special provision if an accredited applicant body makes major modifications to its operations or if other changes take place which could affect the basis of its accreditation.

G.3.5.5. At each surveillance the accreditation body should check the following and have an interview with responsible management:

- the effectiveness of the applicant body's operations with regard to achieving the objectives of Guides 62, 65 and/or 66 or other normative document;
- the functioning of internal audits and procedures for notifying management of any nonconformities;
- customer complaints;
- changes to the documented system;
- areas subject to change;
- progress of planned activities aimed at continual improvement of operational performance;
- follow up of conclusions resulting from internal audits;
- action taken on nonconformities identified during the last accreditation assessment;
- use of accreditation marks.

G.3.5.6. During surveillance accreditation assessments accreditation bodies shall check where any nonconformity or failure to meet the requirements of accreditation is revealed, e.g. by a complaint, that the applicant body has investigated its own systems and procedures and taken appropriate corrective action.

G.3.5.7. Reassessment is a requirement of Guide 61. The purpose of re-assessment is to verify overall continuing effectiveness of the accredited body's processes and management system in their entirety. The interval between initial assessment and re-assessment and between re-assessments shall not exceed 60 months (5 years). A recommended interval is 48 months (4 years). The re-assessment shall provide for a review of past performance over the period of the accreditation. The re-assessment programme should take into consideration the results of the above review and shall at least include a review of the management system documents and a site assessment (which may replace or extend a regular surveillance visit). It shall at least ensure

- a) the effective inter-action between all elements of the system;
- b) the overall effectiveness of the system in its entirety in the light of changes in operations;
- c) demonstrated commitment to maintain the effectiveness of the system.

G.3.5.8. In addition to the information specified in guidance G.3.4.1. to G.3.4.4, reports of surveillance and reassessment visits should contain a report on the clearing of each nonconformity revealed previously.

G.3.5.9. The accreditation body should define the basis on which it evaluates performance and utilizes witness audits. The extent and character of the witnessing should be based on the number and complexity of the accredited scope categories, taking into account the volume of relevant business and any other significant factors.

G.3.5.10. Accreditation bodies shall evaluate the performance of certification/registration body audit teams on a regular basis, in order to evaluate the continued effectiveness of the certification/registration body's audit programme management. This can be done through a combination of techniques, such as witnessing, analysis of client feedback, post-audit reviews, auditor interviews, auditee interviews.

G.3.5.11. Witnessing is a required part of the surveillance programme, although not necessarily at every surveillance. The extent and character of the witnessing should be based on the number and complexity of the accredited scope categories, taking into account the historical data, the volume, organizational changes and any other relevant factors. Accreditation bodies shall develop a programme of full and partial witness audits in order to develop and maintain confidence in the performance of certification/registration bodies. The accreditation body shall define a programme of full or partial observation that enables the accreditation body to assess the planning, management and conduct of certification/registration audits.

Annex 1 - Witness Audits

This Annex provides Guidance on clauses 3.3 and 3.5 of ISO/IEC Guide 61. See Guidance G.3.3.3 and G.3.5.9.

GA.1. In order that Accreditation Bodies may effectively meet the requirements of Clauses 3.3.2. and 3.5.1. of ISO/IEC Guide 61, accreditation bodies shall require accredited certification/registration bodies to have enforceable arrangements with organisations holding an accredited certificate that commit the holder of the accredited certificate to provide, on request, access to accreditation body assessment teams to witness the certification/registration body's audit team performing an audit at the organisation's site.

Annex 2 – Cross-Frontier Accreditation

1. PRINCIPLE

- A. This Annex provides guidance on Section 3 of ISO/IEC Guide 61 for the accreditation of management system certification/registration bodies.
- B. This Annex is intended to strengthen the international network of accreditation bodies (ABs) for certification/registration bodies (CRBs) provided through IAF. It should assist the World Trade Organization Technical Barriers to Trade agreement (WTO/TBT) (as well as other regional trade agreements) objective of facilitating international trade by removing technical barriers to trade through mutual recognition between the national based conformity assessment systems.
- C. For this to be achieved, the ABs operate as a network, each providing an equivalent accreditation service.
- D. The signatories to the IAF Multilateral Recognition Arrangement (MLA) normally operate from a national base, providing accreditation of CRBs for their home market. The effect of the IAF MLA, based on IAF peer evaluation, is that the accredited CRBs should receive recognition from the whole global market for the certificates of conformity that they issue under their scopes of accreditation.
- E. There are however situations where CRBs will seek more than one accreditation, or a “foreign” accreditation, and it is the CRB’s right to do so. Nevertheless, IAF strongly encourages CRBs to have local country accreditation whenever it is available. (Only when all countries or economies have ABs that are signatories of the IAF MLA, and when the user market has fully recognized and accepted the mutual recognition behind the IAF MLA, is the market likely to cease its demands for multiple accreditation.) IAF’s objective is to offer its mechanism for mutual recognition so that duplicate accreditation will no longer be looked for in the market place.
- F. Reasons why a CRB may seek accreditation from bodies outside its own country or economy instead of, or as well as, the local country accreditation include:
 - The local AB(s) do(es) not offer the complete required scope of accreditation (including Standards and sector schemes);
 - The local AB(s) is/are not a signatory/signatories to the IAF MLA;
 - There is no local AB in the country or economy;
 - CRBs’ preferences based on commercial or other business reasons;
 - The CRB’s customers demand a specific accreditation and will not be persuaded to accept an equivalent;

- The CRB is part of a chain of CRBs with a single owner who wants all the CRBs to be able to offer the same accredited certification/registration;
- Regulatory requirements within a specific country or economy require accreditation by a specific AB.

G. In the above and similar circumstances, an IAF MLA signatory, if asked to provide accreditation to a CRB outside its country or economy, may respond positively. However the following steps should be considered before accepting the contract:

G.1. If there is an IAF MLA signatory/signatories covering the scope of the required accreditation in the country or economy of the applicant CRB, the foreign IAF MLA signatory AB should:

- enquire whether the applicant is aware of the local IAF MLA signatory AB(s) and whether local accreditation is held;
- suggest that the accreditation could be more economically performed by a local IAF MLA signatory AB; and
- point out the equivalence of the local accreditation demonstrated through the IAF MLA.

G.2. If the applicant CRB chooses a foreign MLA signatory AB instead of a local IAF MLA signatory AB, the foreign AB should:

- inform the local IAF MLA signatory AB(s) that it will be undertaking the work and explain the circumstances after seeking permission for this from the applicant CRB;
- utilize a local IAF MLA signatory AB to provide assessment team personnel wherever possible; and
- propose a joint assessment with a local IAF MLA signatory AB if the applicant CRB is interested in longer term involvement of the local IAF MLA signatory AB and/or local accreditation.

NOTE: If permission sought from the CRB under the first bullet above is not obtained, this does not prevent the foreign MLA signatory approaching local MLA signatories as sources of assessment personnel at the stage when the assessment team is being put together (see Section 5.1 of Implementation).

G.3. If the applicant chooses a foreign MLA signatory AB as well as a local IAF MLA signatory AB, the foreign AB should: take account of the results of the assessments of the local AB when planning its assessment programme for the CRB; and

- obtain written permission from the CRB to share information gained through its accreditation activities with the local AB. (See IAF Procedure for Exchange of Documentation among IAF MLA Accreditation Bodies.); and
- take account of the results of the assessments of the local AB when planning its assessment programme for the CRB.

H. In all of the above cases, the objective of a potential transfer of the accreditation, within a reasonable timeframe, with the agreement of the CRB, to the relevant local IAF MLA signatory AB, should be borne in mind.

I. One aim of this Guidance is to give confidence to the local national market in the activities of a foreign IAF MLA signatory AB. To achieve this, there is not only need for adequate technical control (with the support of local assessors, knowledgeable in the language, culture, etc.), but also, and more importantly, there is need for assurance that the decisions taken by the foreign AB regarding a local branch of a CRB give due consideration to the fact that the latter is operating *de facto* as a local CRB in that market.

This means that any problem identified should be evaluated from a local as well as a global perspective, so that effective actions can be taken against all non-conforming behaviour (for example, if branch impartiality problems are found in just one country during a worldwide surveillance process, such problems may be minor from the global perspective of the CRB's activities, but critical at the local level).

2. IMPLEMENTATION

2.1. Control of accredited certification/registration in foreign countries

2.1.1. IAF MLA signatory ABs should record the countries in which each CRB accredited by them issues certificates under their accreditation. This includes:

- countries into which accredited certificates are issued directly from the CRB's head or other office; and
- countries in which the CRB operates from local offices, whatever the legal relationship of such offices with the parent CRB.

2.1.2. The recording of these countries is not for the purpose of granting prior permission to the CRBs to issue accredited certificates in these countries, but in order that the IAF MLA signatory AB can plan its assessment programme for each of its accredited CRBs with up-to-date knowledge of the full geographical scope of the CRB's activities.

2.2. Critical locations

2.2.1. IAF MLA signatory ABs should require their accredited CRBs to identify to them those physical locations (see ISO/IEC Guide 61 clause 3.1.2.2 b), whatever the composition (office, person etc) or legal relationship (contractor, franchisee etc) of such location with the CRB, where activities are conducted or controlled that determine or demonstrate the effectiveness of the CRB's performance of the accredited certification/registration, in particular:

- the process for initial qualification, training and ongoing monitoring of auditors and assessment personnel records; or
- the application review, the assignment of assessment personnel, and/or review of the final report; or
- the certification/registration decision based on the final review of the assessment report.

2.2.2. Locations as described under 3.1.1 above are referred to as "critical locations" below.

2.3. Assessment of foreign critical locations

NOTE: This and the subsequent Section of this document address the situation where a foreign AB operates outside its own country. See the preceding Principle section of the document for the reasons why this situation exists and therefore has to be managed.

2.3.1. IAF MLA signatory ABs should have an assessment programme that covers all the critical locations of its applicant and accredited CRBs that are identified to them under Section 3 above, wherever in the world they may be. This programme may utilize local country IAF MLA signatory ABs, but should not allow for sampling of the initial assessment of critical locations.

2.3.2. IAF MLA signatory ABs should require CRBs to have documented procedures that demonstrate to the AB that any new foreign critical location active in the provision of its accredited service is set up in such a way as to meet its accreditation requirements before the AB authorizes the issue of its accredited certificates, either directly from the foreign critical location or resulting from certification/registration work performed under the control of the foreign critical location.

2.3.3. A visit by the foreign AB prior to authorization is not always required, but all critical locations should be assessed on site, either directly by the foreign AB or under appropriate arrangements (e.g. with a local IAF MLA signatory) to confirm that its accredited service may be offered resulting from the work of the critical location.

2.3.4. As well as direct assessment of the critical locations in foreign countries, IAF MLA signatory ABs should assess the effectiveness of the management control, by the head office of the CRB, over the activities of its foreign critical locations.

2.3.5. Follow-up assessment (surveillance and reassessment) visits at the critical location should normally take place at the same frequency as at an equivalent single site CRB. The frequency of surveillance visits may be reduced, subject to absence of justifiable complaints, by taking account of factors such as:

- Low levels of work being undertaken;
- Justifiable confidence, based on access to information demonstrating the work undertaken, in the management control over the operations of the critical location by the head office of the CRB;
- Access, secured by formal agreement, to the assessment results relative to the activities carried out at the critical location by other IAF MLA signatory ABs.

2.4. Assessment of CRBs by foreign IAF MLA signatory ABs where the CRB is not accredited by a local IAF member accreditation body

2.4.1. Where the foreign CRB or its critical location is not accredited, or applying for accreditation, by a local IAF member AB, the foreign AB should either propose use of any local IAF member AB as subcontractor for appropriate parts of the assessment or invite assessment personnel from any local IAF member AB to participate as a member of its team for the assessment of the CRB's local activities.

2.4.2. The participation of such a local assessor as a team member in the foreign AB's team is subject to the normal right to appeal by the CRB (ISO/IEC Guide 61, clause 3.2.4).

2.4.3. For a local assessor to participate as a team member in a foreign AB's assessment team, he/she should receive appropriate training, supervision and monitoring from the foreign AB, and have normal team member duties assigned to him/her so that he/she can play a full part in the assessment team.

2.4.4. In addition to the normal assessment team responsibilities, the local assessor may be assigned special duties with regard to aspects of the assessment that are influenced by local issues and conditions, such as investigation of complaints and conflict of interest issues.

2.4.5. In the event that a local assessor participates as a team member, his/her costs will be covered through the CRB's payment to the foreign AB for the assessment. The foreign AB is responsible for recovering the costs associated with training etc (see Section 5.3 above).

2.5. Assessment of CRBs by foreign IAF MLA signatory ABs where the CRB is accredited by a local IAF member accreditation body

2.5.1. Where the activity of the CRB performed by a local physical location is either accredited by a local IAF member AB or subject to application for such accreditation, the foreign AB should cooperate as far as is practicable with the local IAF member AB, including taking full account of its work whenever this is justifiable, as long as this is acceptable to the CRB. This may be through formal subcontracting arrangements, or through joint assessment activity, or by other means.

2.6. Communication and Arrangements between IAF MLA Signatory ABs

2.6.1. For effective implementation of this Annex, frequent and good communication amongst IAF MLA signatory ABs is critical, e.g. with respect to complaints handling, notification of sanctions, and changes in accreditation scopes.

2.6.2. Defined arrangements between IAF MLA signatory ABs are also necessary to meet the requirements of clause 2.1.3 of ISO/IEC Guide 61, e.g. through subcontracting arrangements and arrangements for joint assessment activity.

End of IAF Guidance to the Application of ISO/IEC Guide 61

Further Information

For further Information on this document or other IAF documents, contact any member of IAF or the IAF Secretariat.

For contact details of members of IAF see - IAF Web Site - <<http://www.iaf.nu>>

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